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(54) **PERCUTANEOUS ACCESS FOR SYSTEMS AND METHODS OF TREATING SLEEP APNEA**

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A61N 1/05	(2006.01)

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CPC ***A61N 1/3601*** (2013.01); ***A61N 1/0504*** (2013.01); ***A61N 1/0551*** (2013.01); *A61N 1/0553* (2013.01); *A61N 1/0556* (2013.01); *A61N 1/0558* (2013.01)

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CPC A61N 1/04; A61N 1/0504; A61N 1/0558; A61N 1/057; A61N 1/0551; A61N 1/0573; A61N 1/0578; A61N 1/058; A61N 1/0587; A61N 1/059; A61N 1/3605; A61N 1/36078; A61N 1/3611; A61N 2001/0578; A61N 2001/058; A61N 2001/0585; A61B 5/6839

USPC 606/129

See application file for complete search history.

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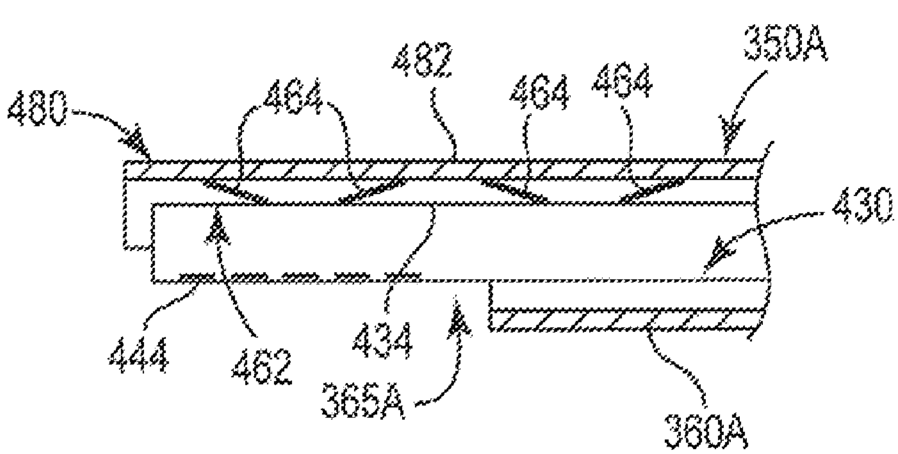
(57) **ABSTRACT**

Systems and methods are described and illustrated for percutaneously implanting a stimulation lead for treating sleep-related disordered breathing.

35 Claims, 18 Drawing Sheets



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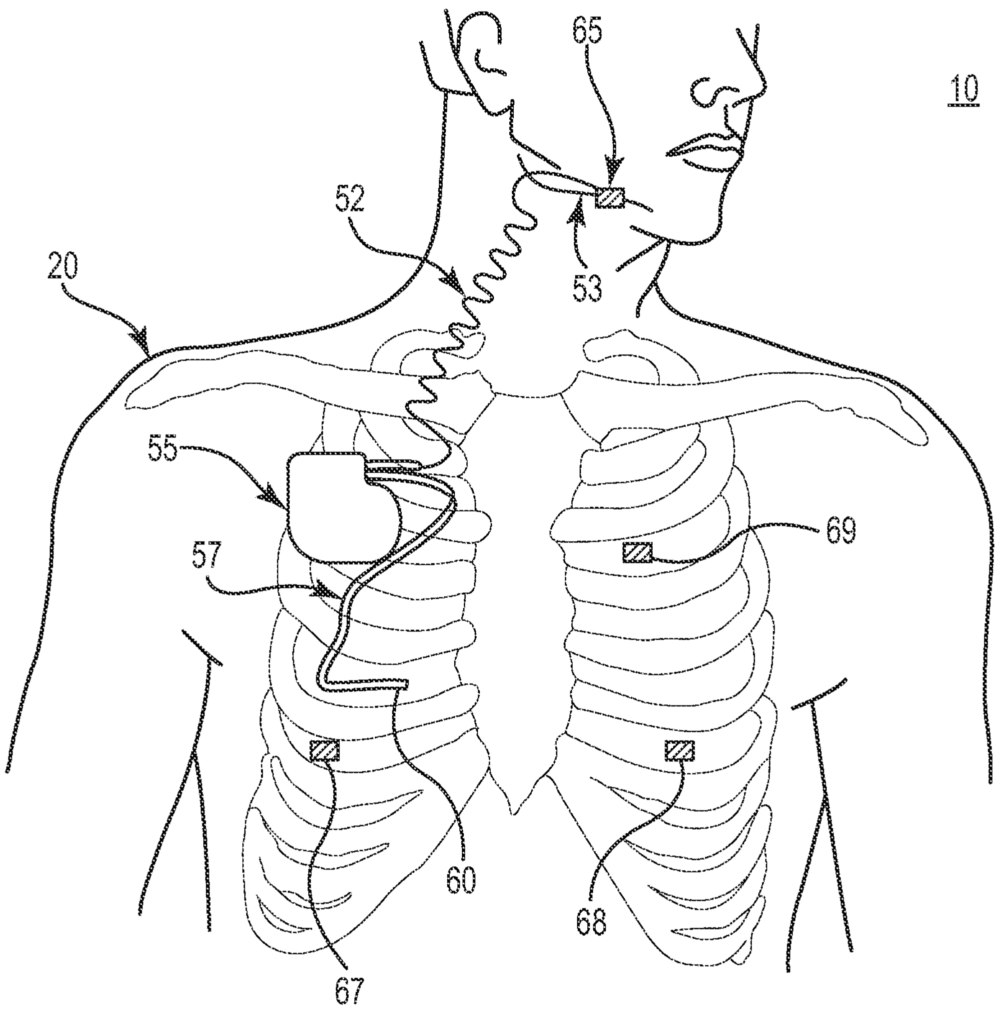
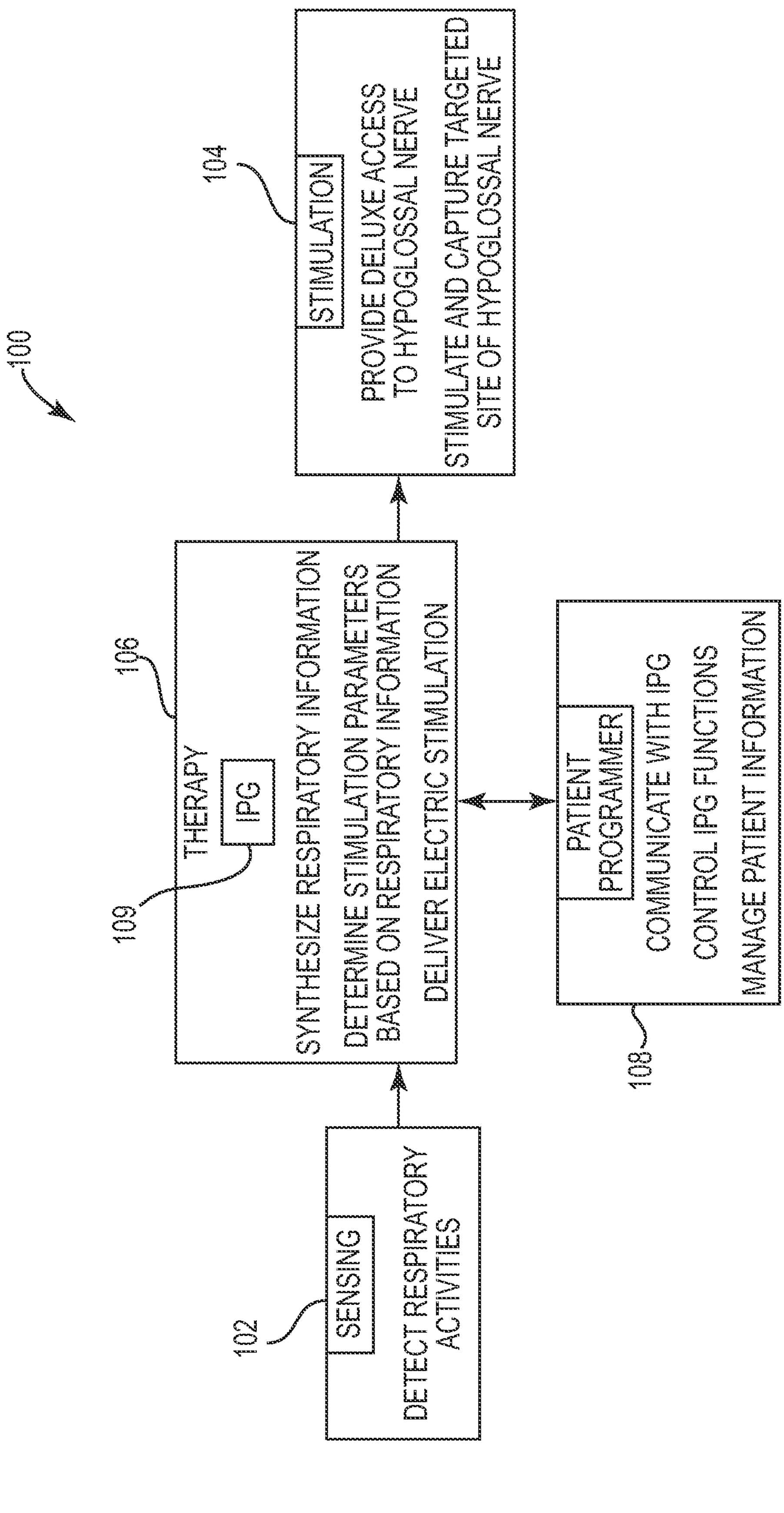


Fig. 1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IPG
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DELIVER ELECTRIC STIMULATION
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COMMUNICATE WITH IPG
CONTROL IPG FUNCTIONS
MANAGE PATIENT INFORMATION
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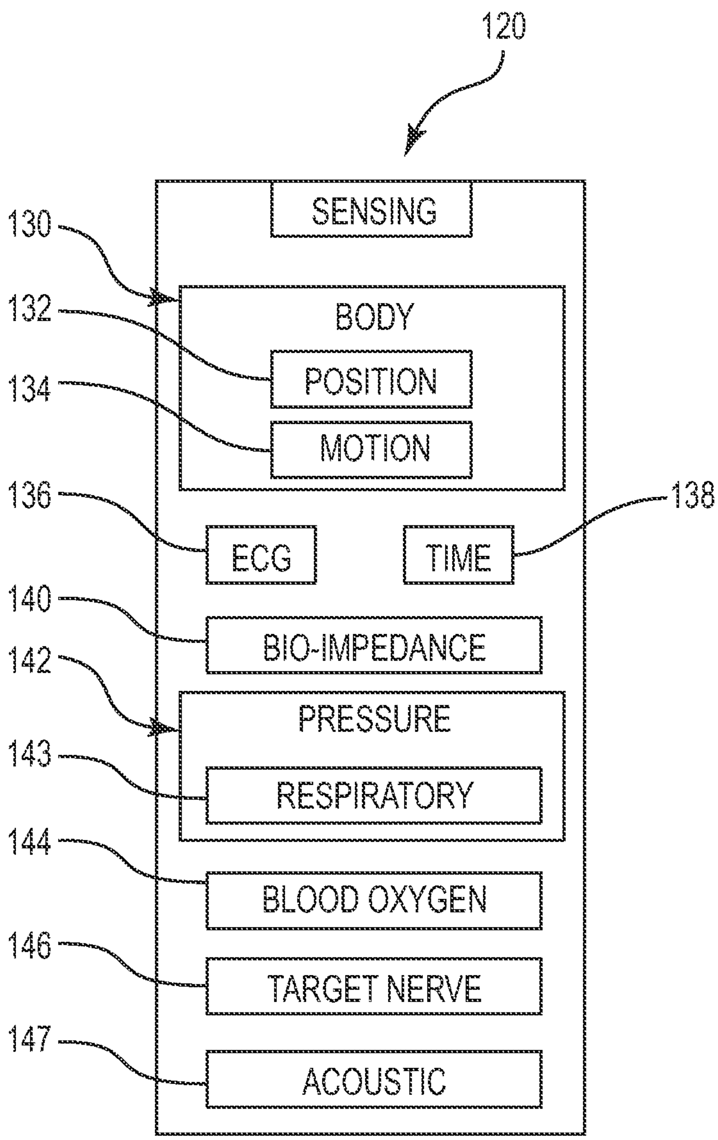
102
SENSING
DETECT RESPIRATORY ACTIVITIES

Fig. 2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SENSING
130
BODY
132
POSITION
134
MOTION
136
ECG
TIME
138
140
BIO-IMPEDANCE
142
PRESSURE
143
RESPIRATORY
144
BLOOD OXYGEN
146
TARGET NERVE
147
ACOUSTIC

Fig. 3

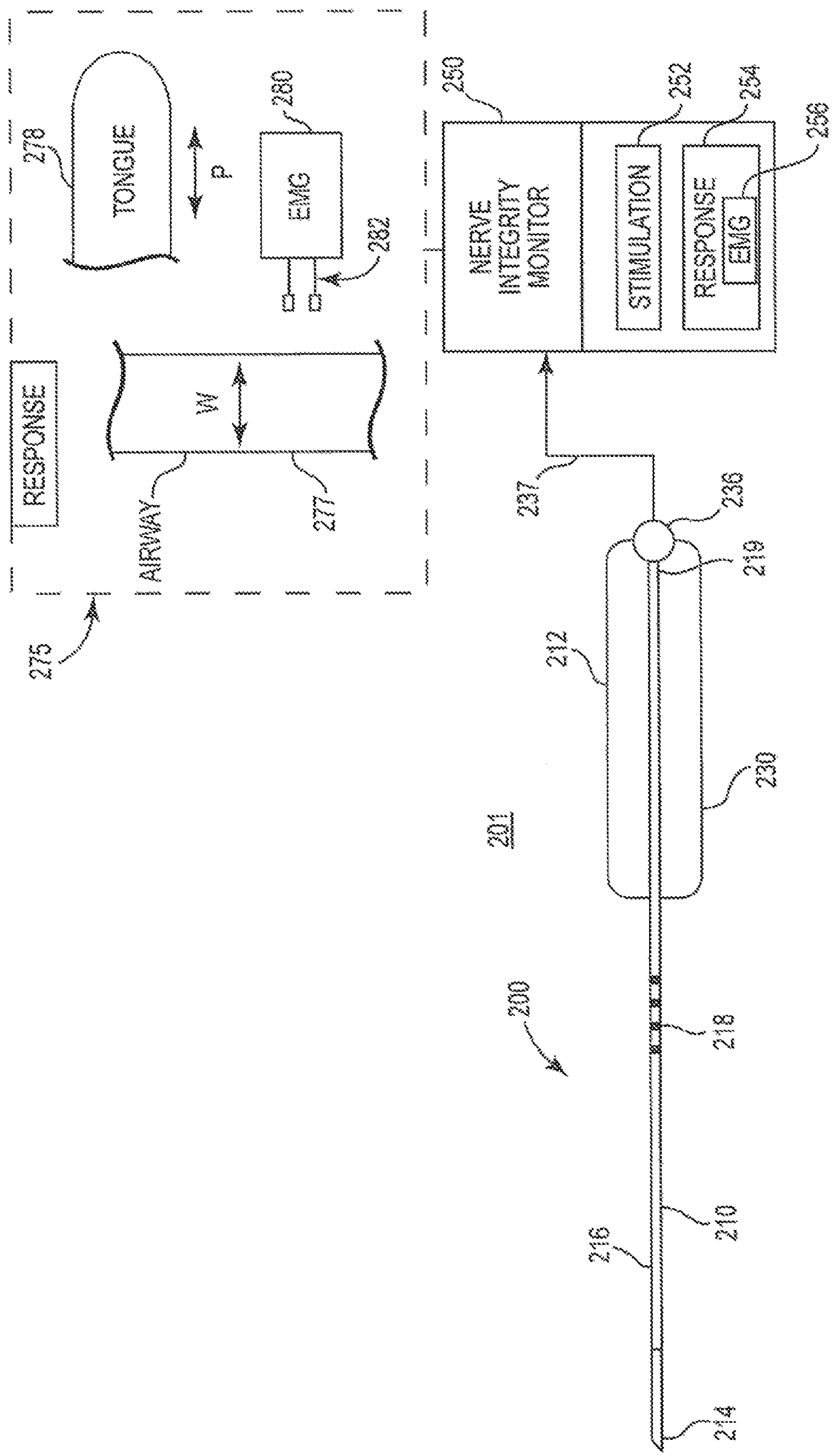

275
RESPONSE
AIRWAY
277
W
278
TONGUE
P
280
EMG
282
250
NERVE INTEGRITY MONITOR
252
STIMULATION
254
RESPONSE
EMG
256
237
236
219
212
230
201
200
218
210
216
214

Fig. 4

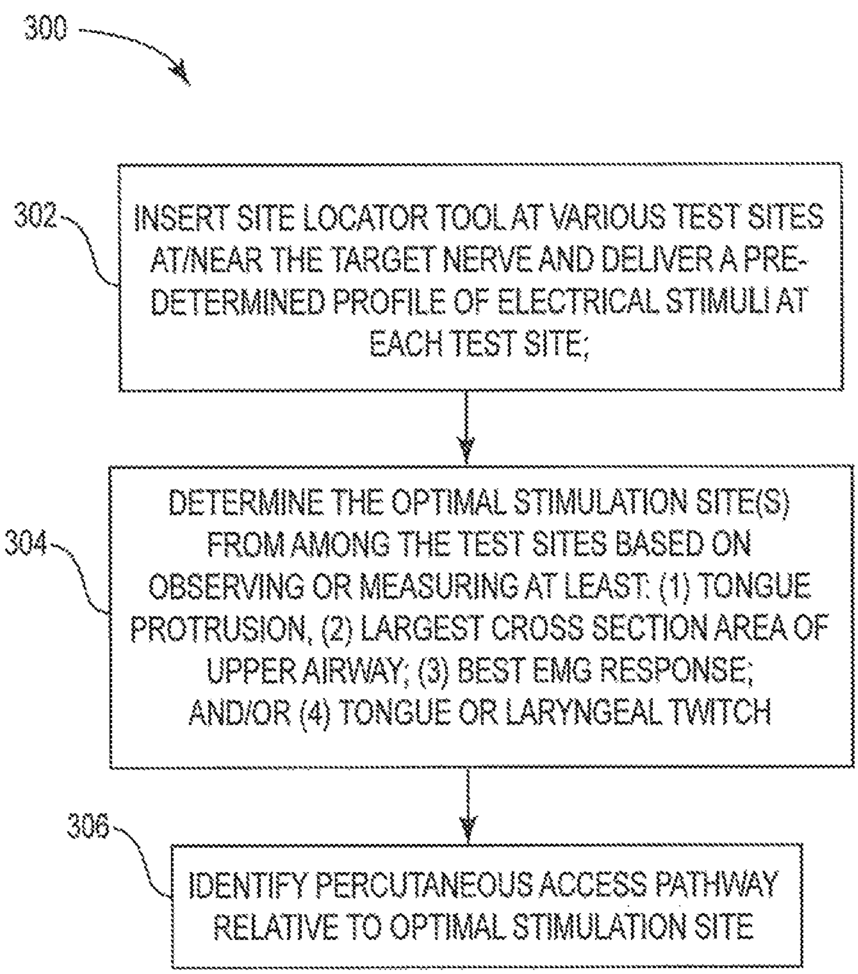

300
302
INSERT SITE LOCATOR TOOL AT VARIOUS TEST SITES AT/NEAR THE TARGET NERVE AND DELIVER A PRE-DETERMINED PROFILE OF ELECTRICAL STIMULI AT EACH TEST SITE;
304
DETERMINE THE OPTIMAL STIMULATION SITE(S) FROM AMONG THE TEST SITES BASED ON OBSERVING OR MEASURING AT LEAST: (1) TONGUE PROTRUSION, (2) LARGEST CROSS SECTION AREA OF UPPER AIRWAY; (3) BEST EMG RESPONSE; AND/OR (4) TONGUE OR LARYNGEAL TWITCH
306
IDENTIFY PERCUTANEOUS ACCESS PATHWAY RELATIVE TO OPTIMAL STIMULATION SITE

Fig. 5

Fig. 6B

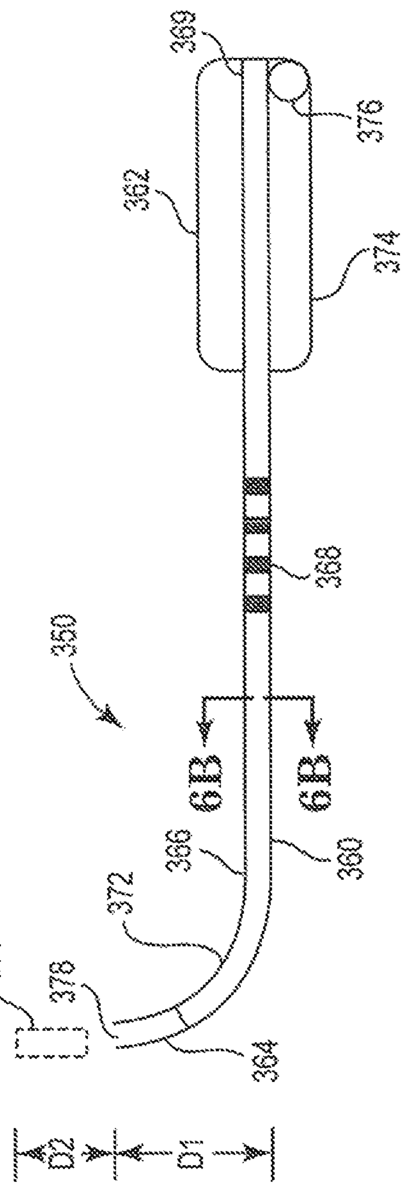


Fig. 6A

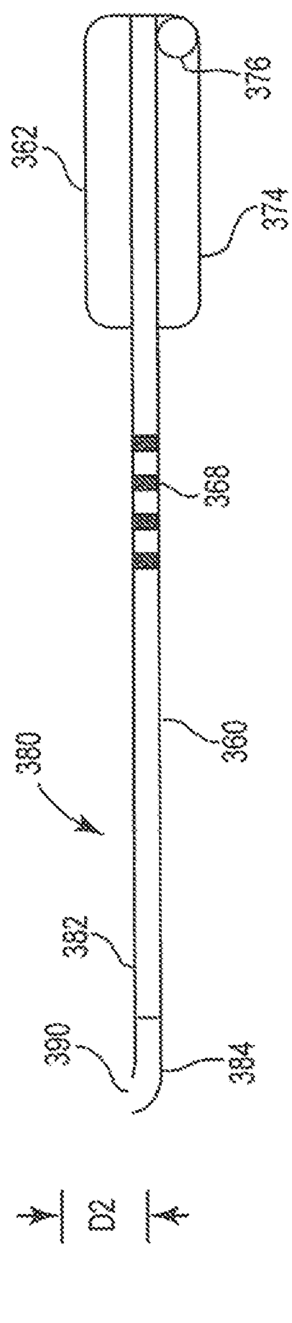


Fig. 6C

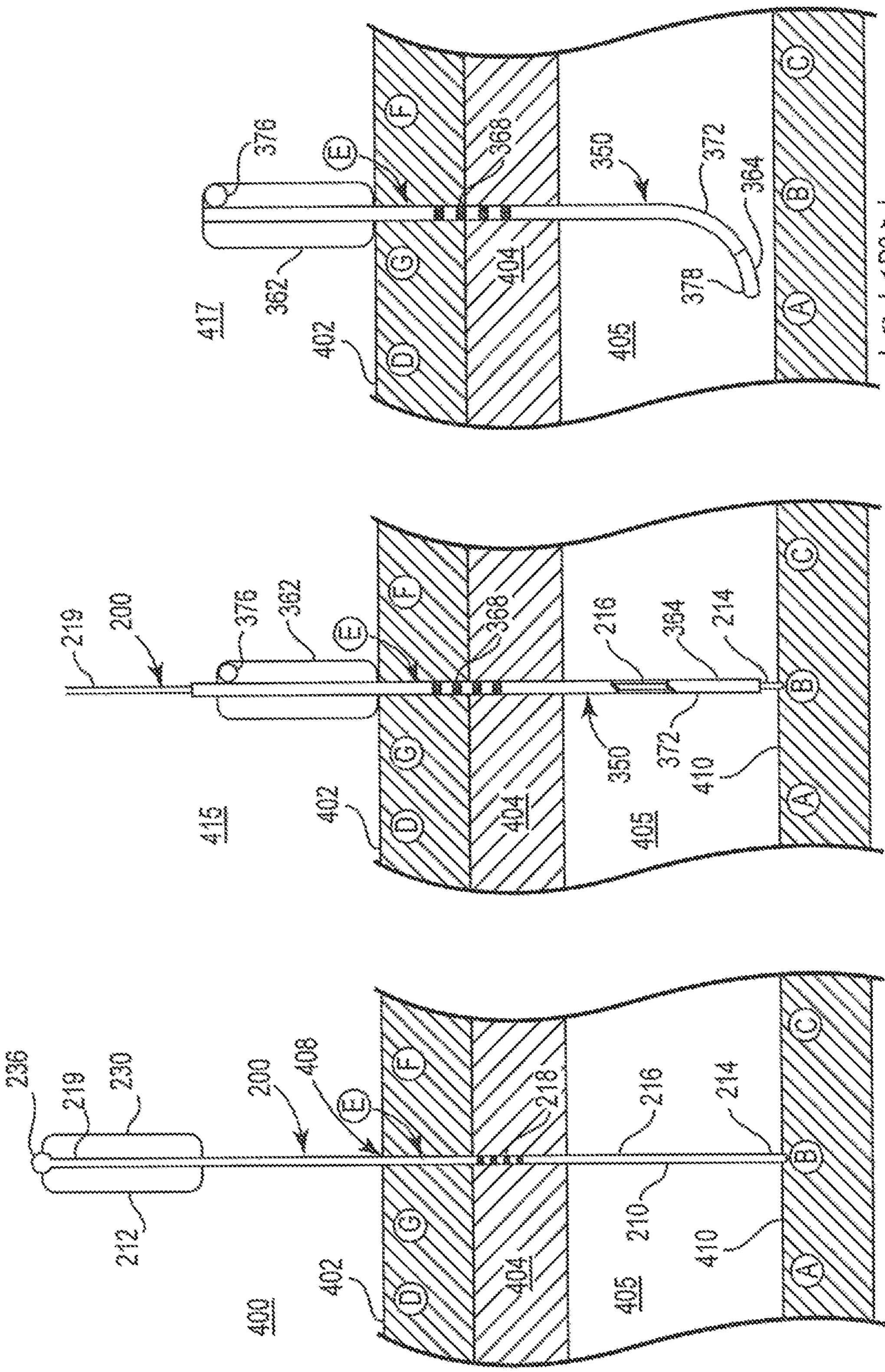
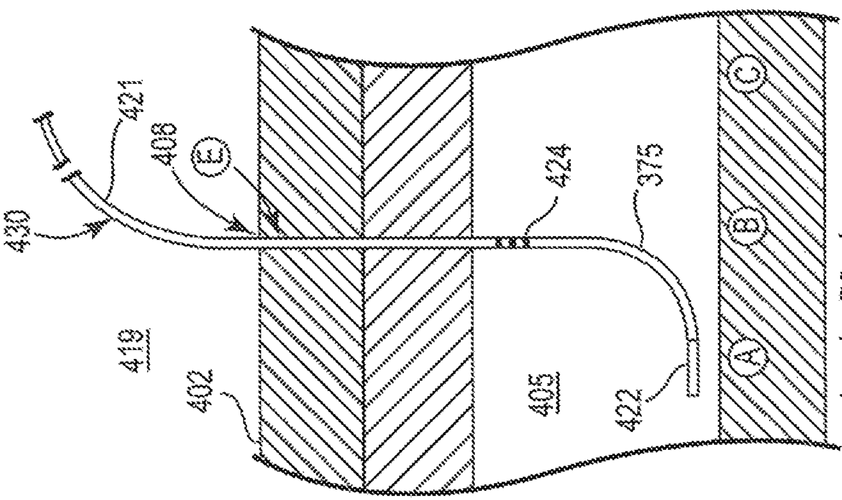


Fig. 7C

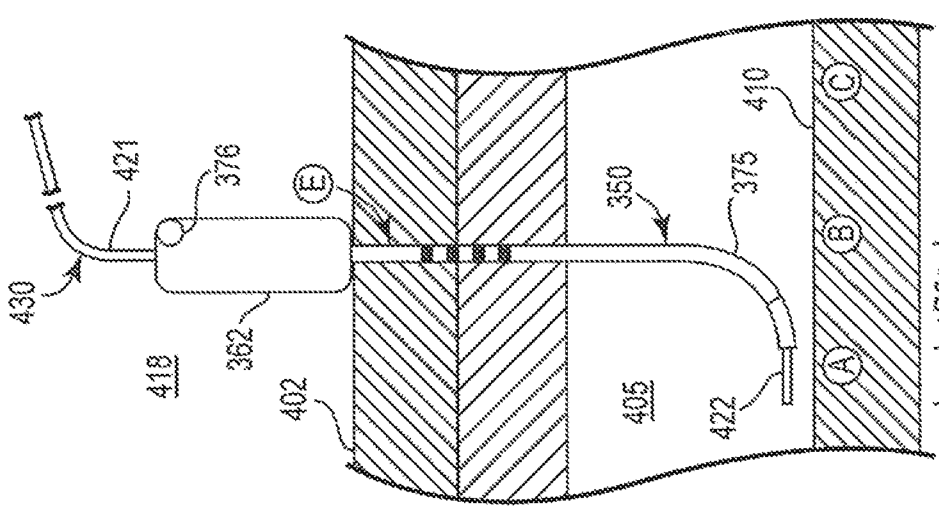
Fig. 7B

Fig. 7A



430
421
408
E
424
375
419
402
405
422
A
B
C
D1
D2

Fig. 7E



430
421
376
E
350
375
410
362
419
402
405
422
A
B
C
D1
D2

Fig. 7D

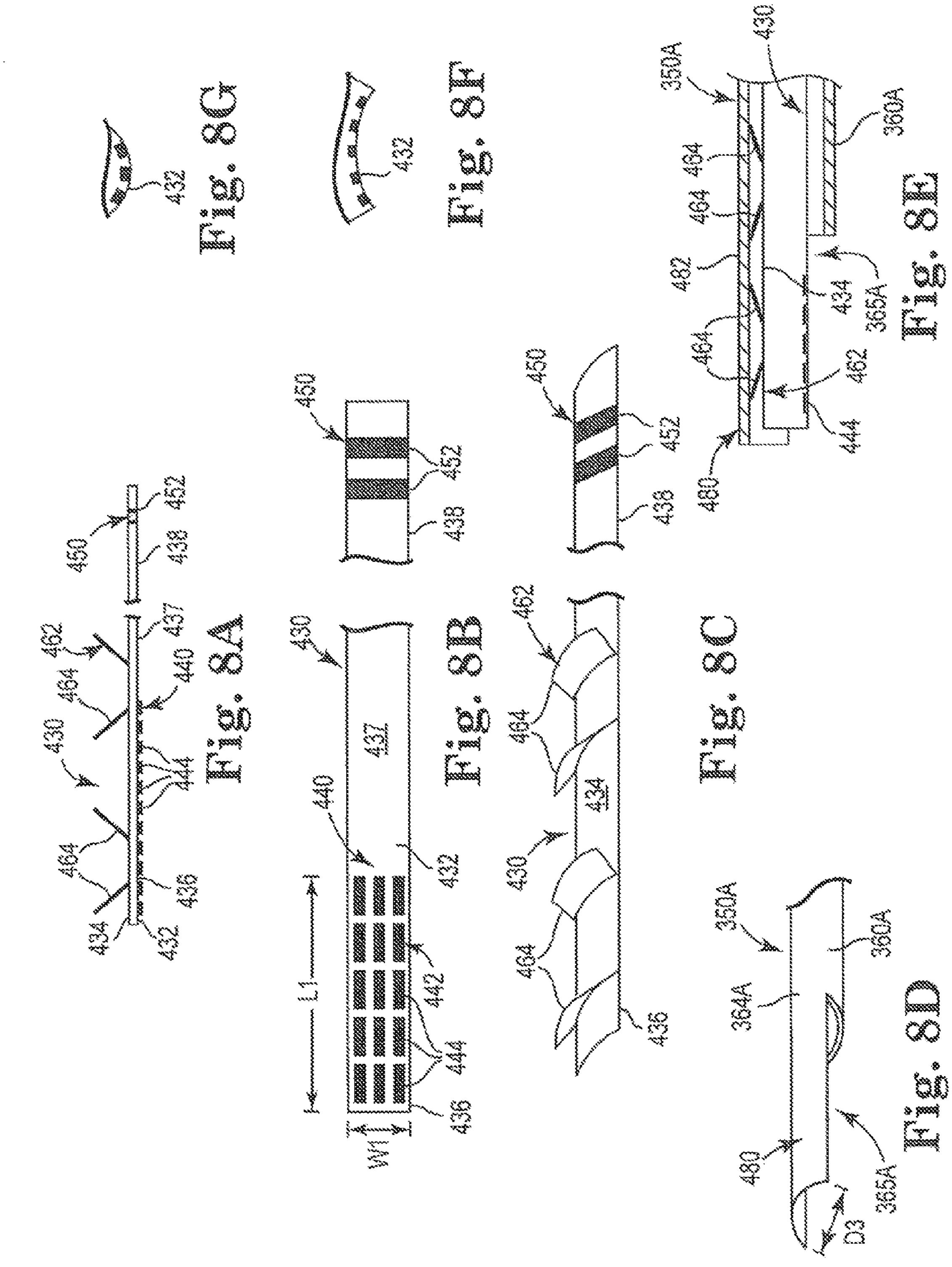


Fig. 8A

Fig. 8B

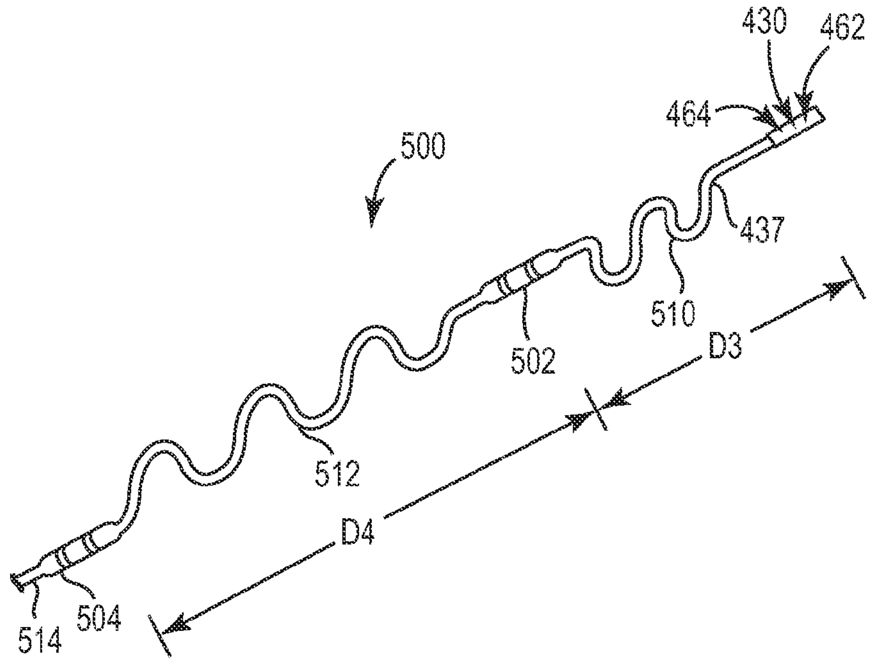
Fig. 8C

Fig. 8D

Fig. 8E

Fig. 8F

Fig. 8G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462
464
500
437
510
502
D3
512
D4
514
504

Fig. 9

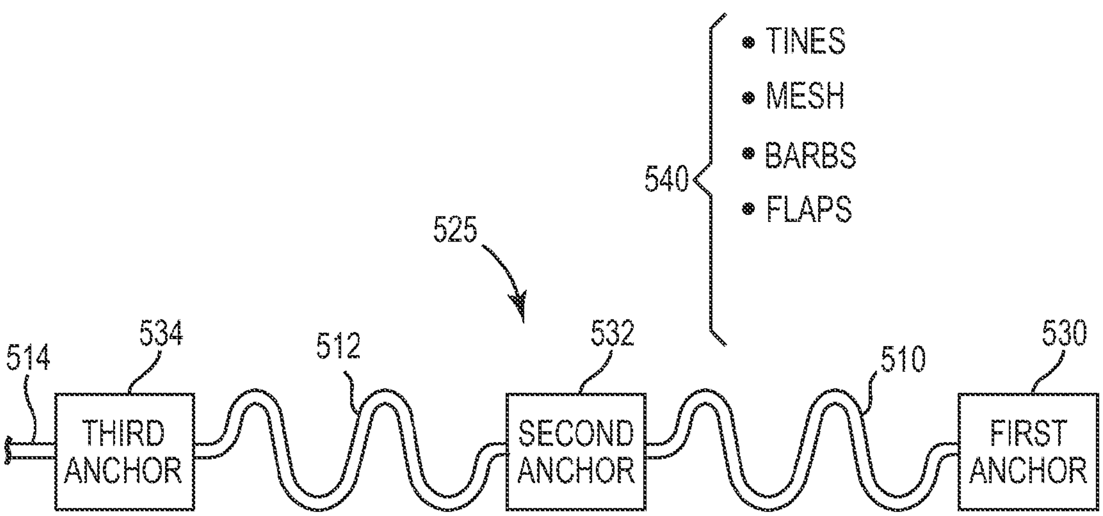
TINES
MESH
BARBS
FLAPS
540
525
514
534
512
532
510
530
THIRD ANCHOR
SECOND ANCHOR
FIRST ANCHOR

Fig. 10

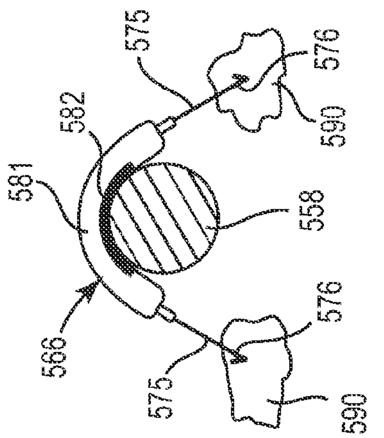

Fig. 14C

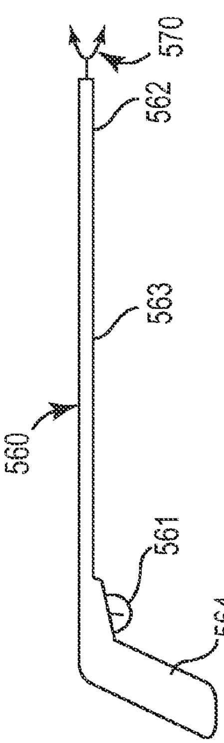

Fig. 12

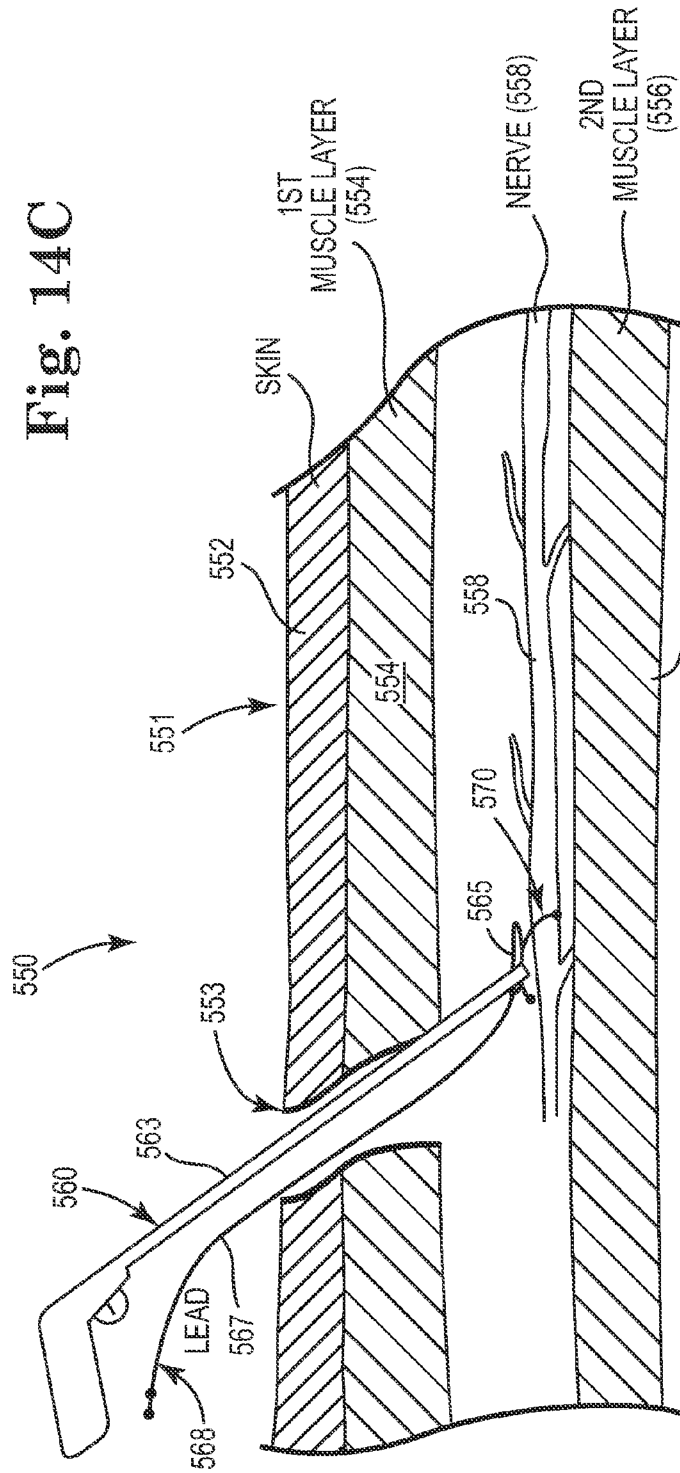

Fig. 11

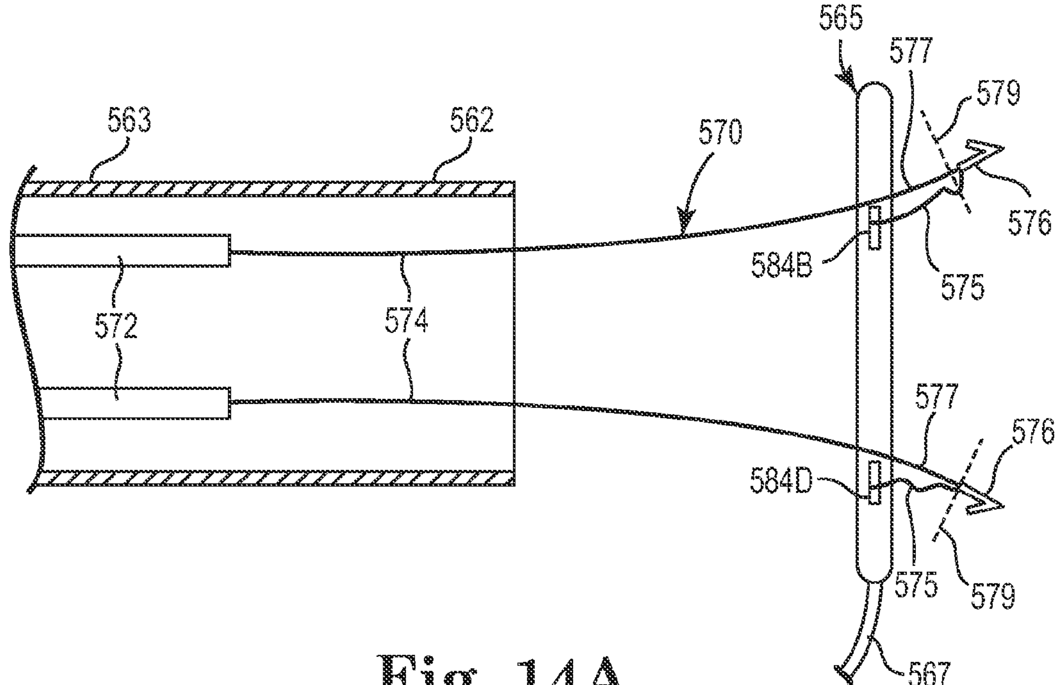

Fig. 14A

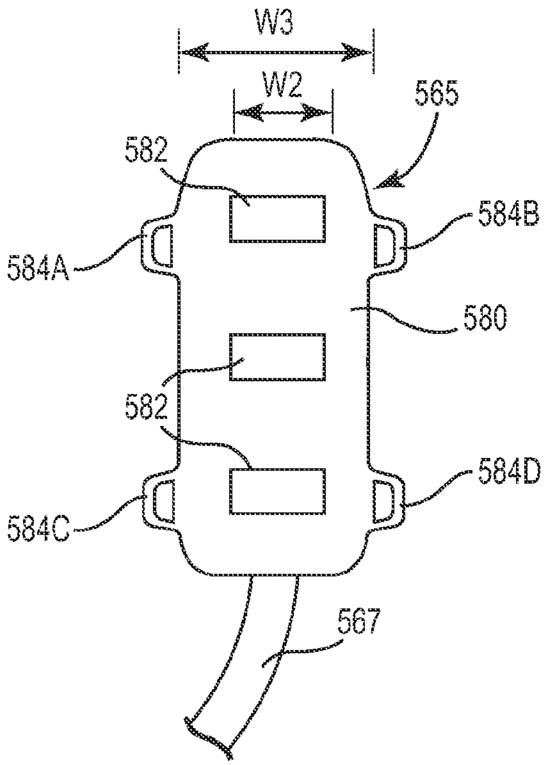

Fig. 13

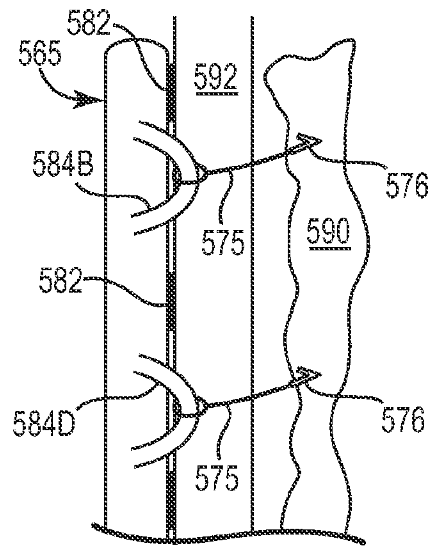

Fig. 14B

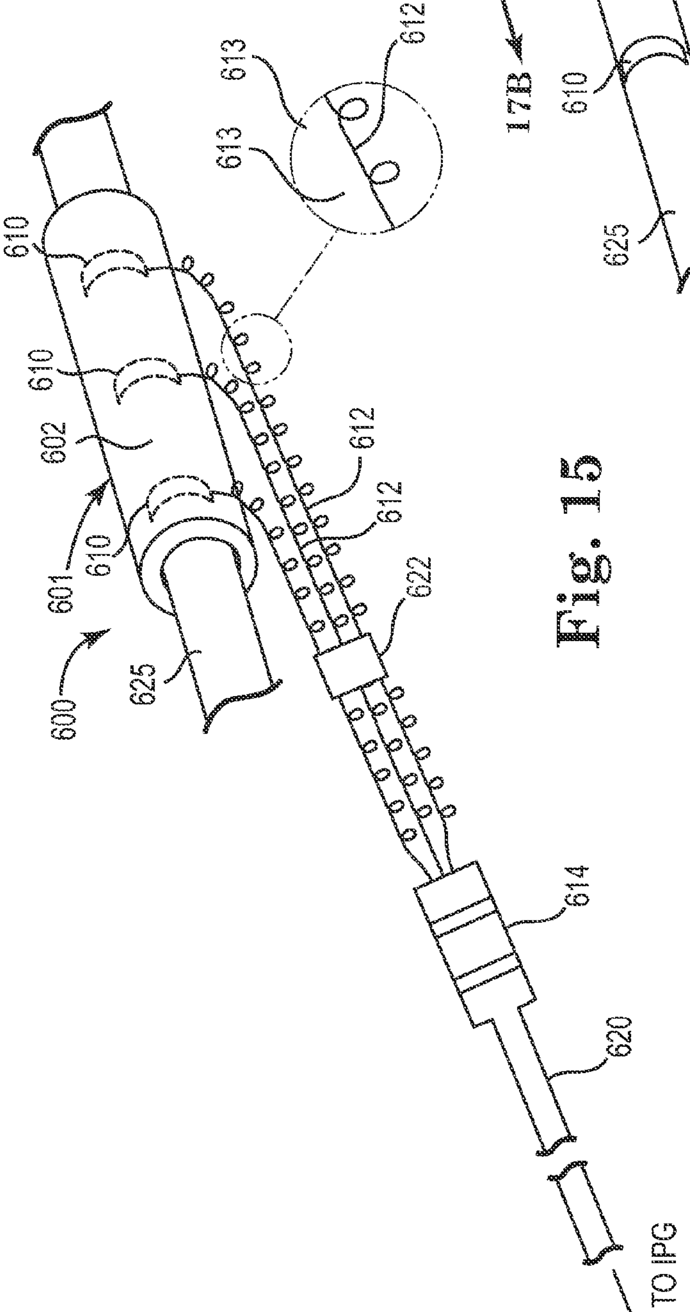
600
601
602
610
610
610
612
612
612
613
613
612
622
614
620
625
TO IPG

Fig. 15

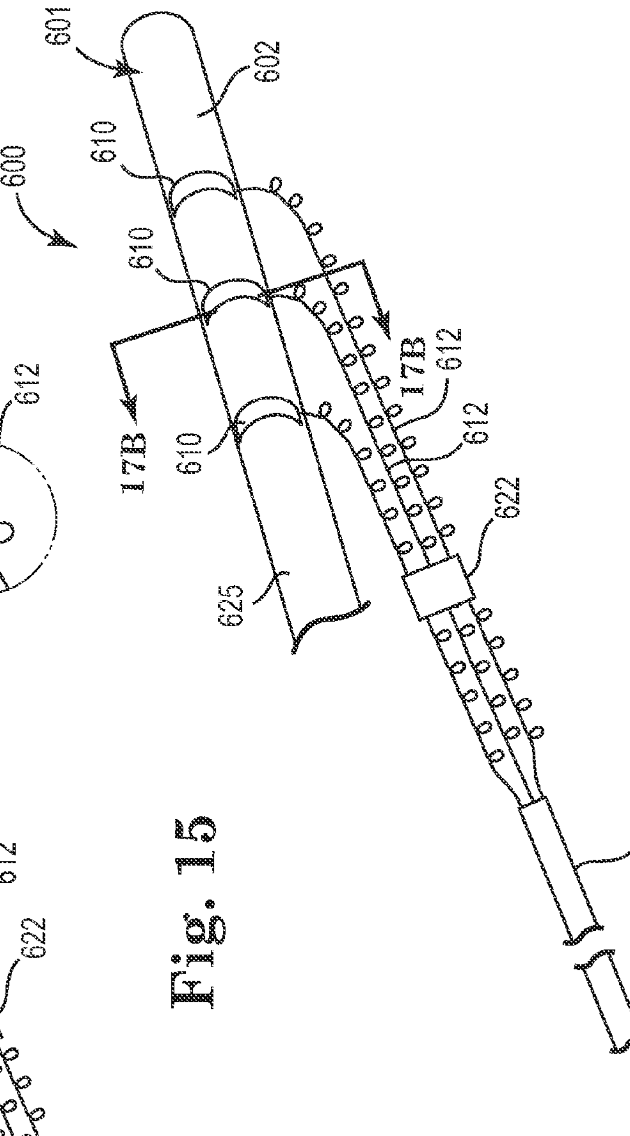
601
602
600
610
610
610
17B
17B
612
612
612
622
625
620
TO IPG

Fig. 16

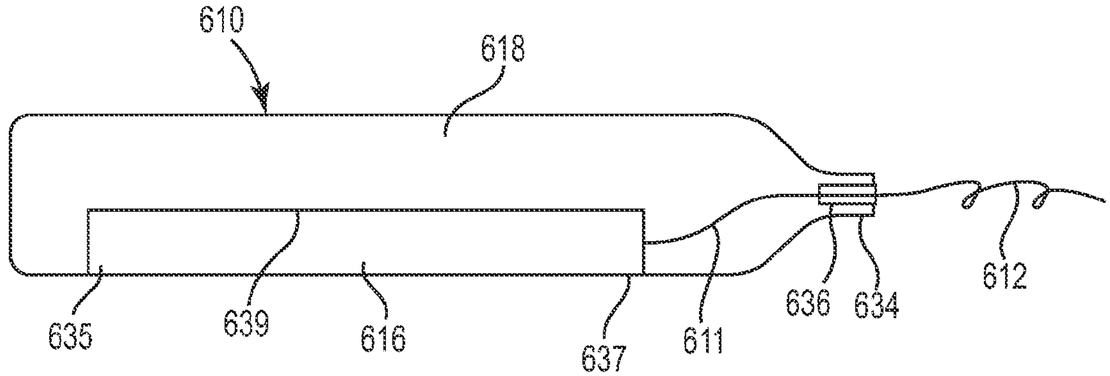

Fig. 17A

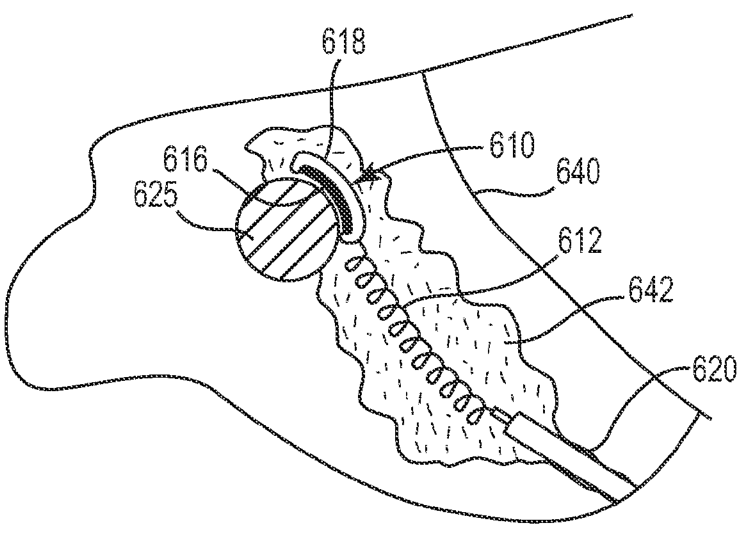

Fig. 17B

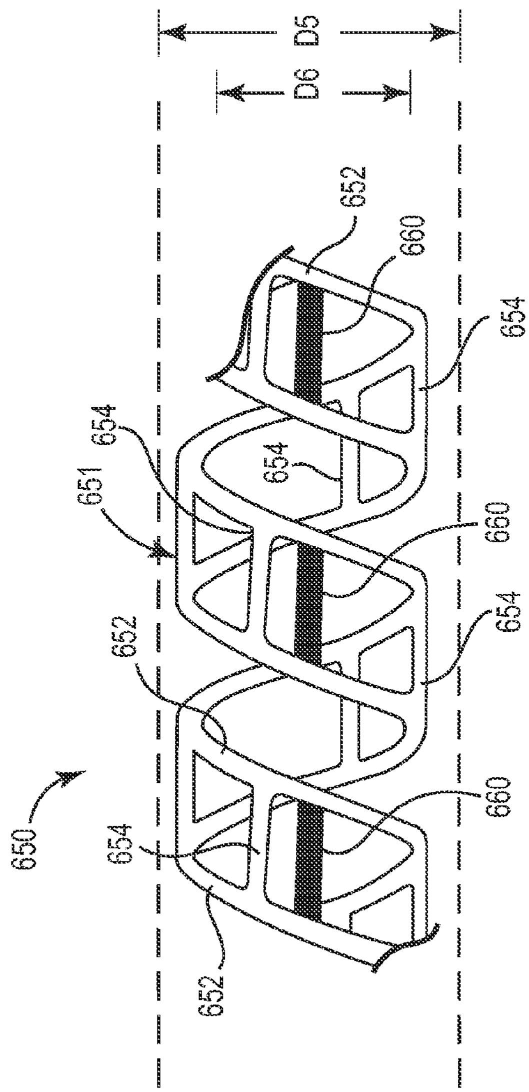

Fig. 18

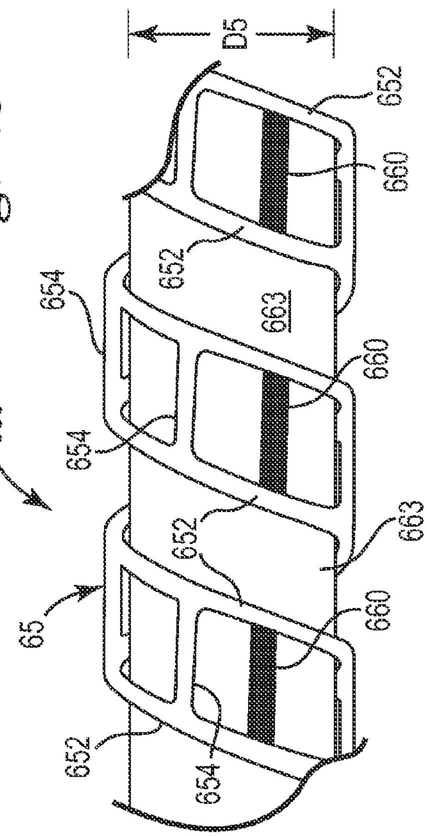

Fig. 19

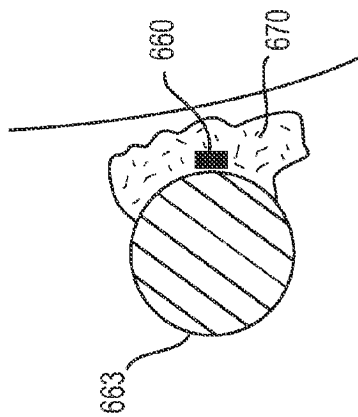

Fig. 20

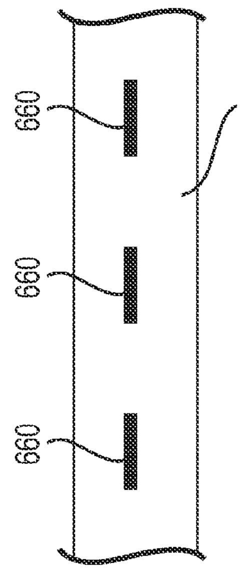

Fig. 21

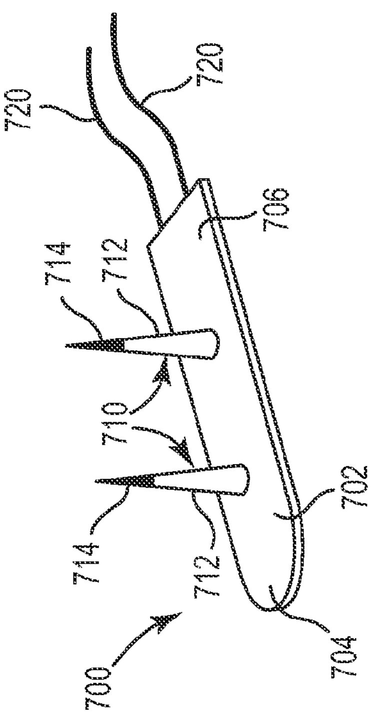

Fig. 22

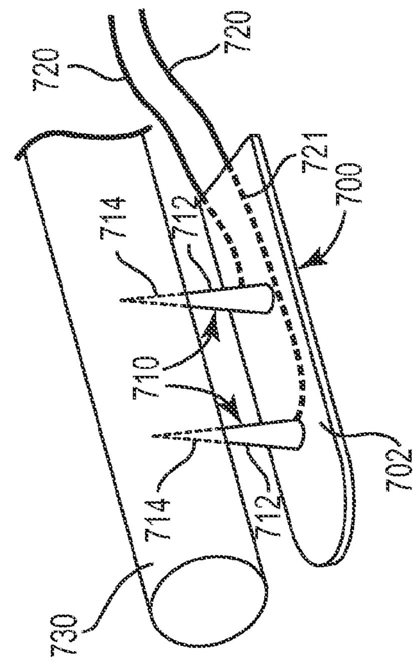

Fig. 23

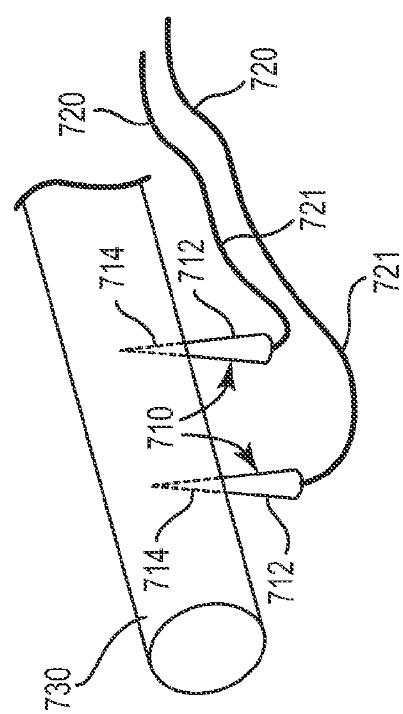

Fig. 24

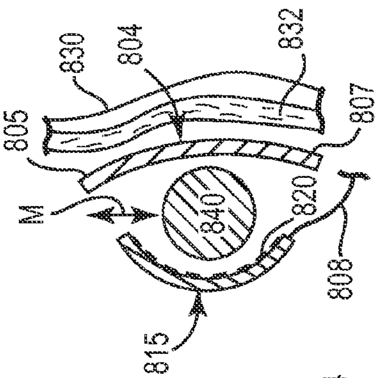

Fig. 27

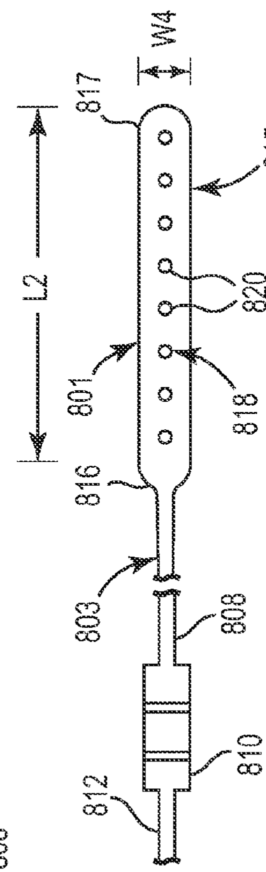

Fig. 25

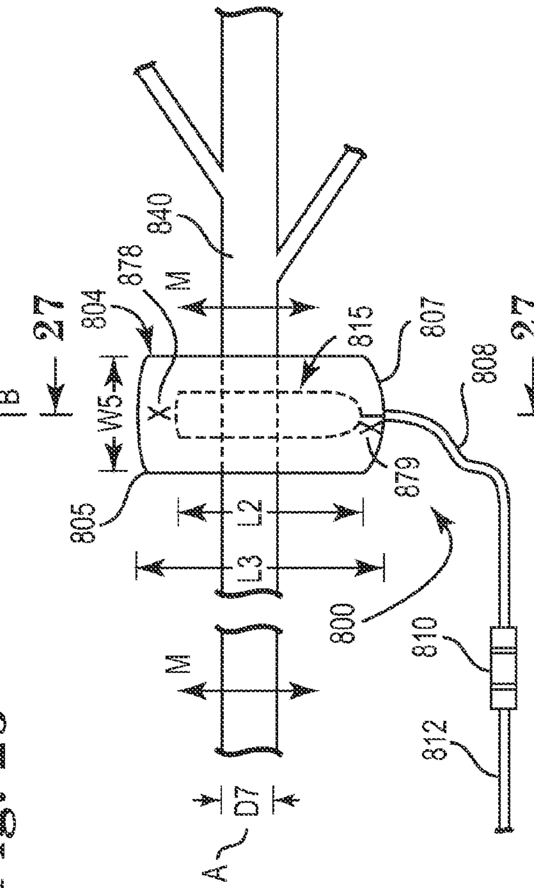

Fig. 26

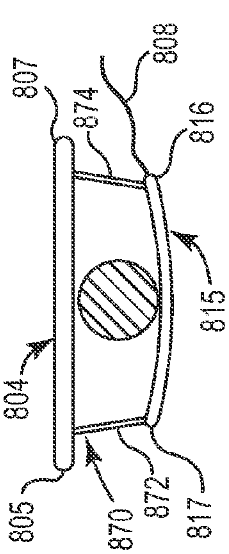

Fig. 29

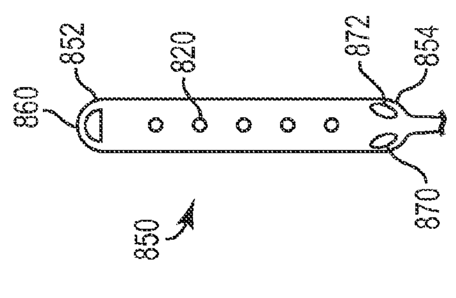

Fig. 28

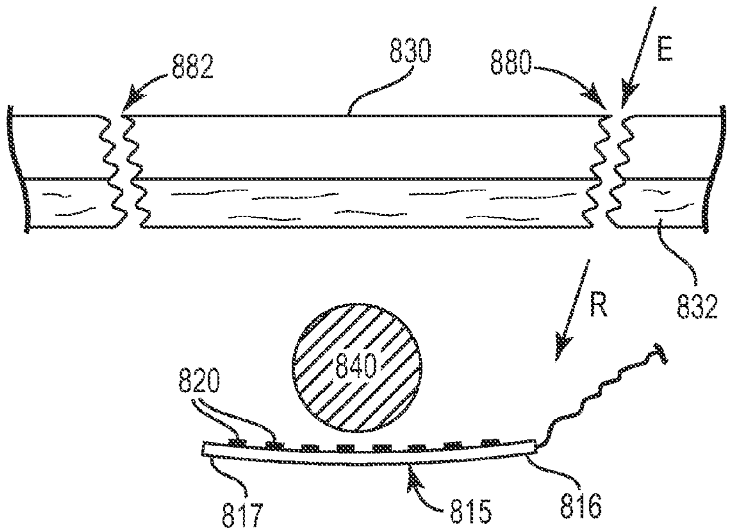

Fig. 30

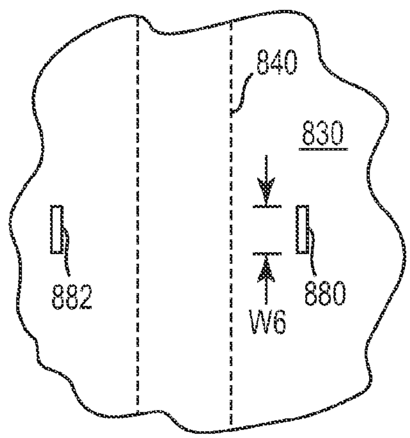

Fig. 31

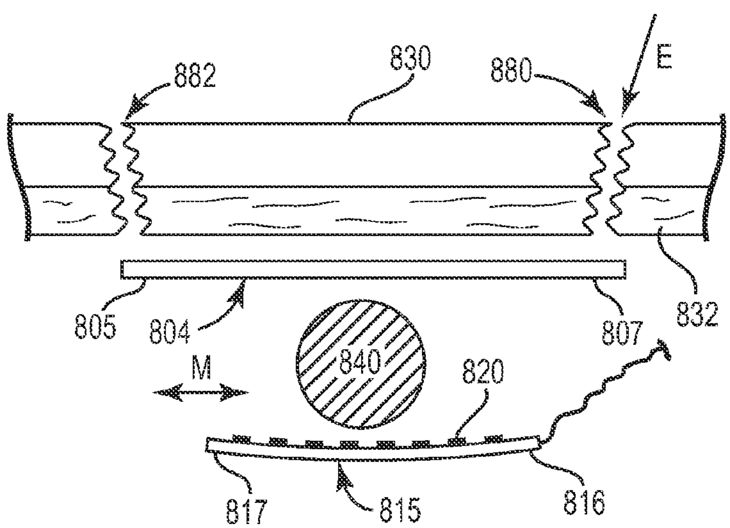

Fig. 32

PERCUTANEOUS ACCESS FOR SYSTEMS AND METHODS OF TREATING SLEEP APNEA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Non-Provisional Application that claims priority to Provisional U.S. Patent Application Ser. No. 61/165,110, entitled "PERCUTANEOUS ACCESS FOR SYSTEMS AND METHODS OF TREATING SLEEP APNEA," having a filing date of Mar. 31, 2009 and PCT Application Serial Number PCT/US10/29253, entitled "PERCUTANEOUS ACCESS FOR SYSTEMS AND METHODS OF TREATING SLEEP-RELATED DISORDERED BREATHING", having a filing date of Mar. 30, 2010, both of which are incorporated herein by reference.

BACKGROUND

The present disclosure relates generally to an implantable stimulation system for stimulating and monitoring soft tissue in a patient, and more particularly, the present disclosure relates to systems and methods of using percutaneous delivery of a stimulation lead to treat sleep-related disordered breathing, such as obstructive sleep apnea and other disorders, and relates to various configurations of a stimulation electrode portion of a stimulation lead.

Sleep apnea generally refers to the cessation of breathing during sleep. One type of sleep apnea, referred to as obstructive sleep apnea (OSA), is characterized by repetitive pauses in breathing during sleep due to the obstruction and/or collapse of the upper airway, and is usually accompanied by a reduction in blood oxygenation saturation.

One treatment for obstructive sleep apnea has included the delivery of electrical stimulation to the hypoglossal nerve, located in the neck region under the chin. Such stimulation therapy activates the upper airway muscles to maintain upper airway patency. In treatment of sleep apnea, increased respiratory effort resulting from the difficulty in breathing through an obstructed airway is avoided by synchronized stimulation of an upper airway muscle or muscle group that holds the airway open during the inspiratory phase of breathing. For example, the genioglossus muscle is stimulated during treatment of sleep apnea by a cuff electrode placed around the hypoglossal nerve.

BRIEF DESCRIPTION OF THE DRAWINGS

Aspects and features of the present disclosure will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the present disclosure when considered in connection with the accompanying drawings, wherein:

FIG. **1** is a schematic illustration of an implantable stimulation system, according to an embodiment of the present disclosure;

FIG. **2** is a schematic illustration of a block diagram of an implantable stimulation system, according to an embodiment of the present disclosure;

FIG. **3** is a schematic illustration of a block diagram of a sensing monitor, according to an embodiment of the present disclosure;

FIG. **4** is a schematic illustration of a percutaneous access system including a site locator tool, a stimulation monitor, and a response evaluation array, according to an embodiment of the present disclosure;

FIG. **5** is a schematic illustration of a method of identifying a stimulation site, according to an embodiment of the present disclosure;

FIG. **6**A is a side plan view schematically illustrating a stimulation lead introduction tool, according to an embodiment of the present disclosure;

FIG. **6**B is a sectional view as taken along lines **6**B-**6**B of FIG. **6**A, according to an embodiment of the present disclosure;

FIG. **6**C is a side plan view schematically illustrating a stimulation lead introduction tool, according to an embodiment of the present disclosure;

FIG. **7**A is sectional view schematically illustrating insertion of a test locator tool, according to an embodiment of the present disclosure;

FIG. **7**B is sectional view schematically illustrating a configuration upon insertion of an introduction tool, according to an embodiment of the present disclosure;

FIG. **7**C is sectional view schematically illustrating a configuration upon removal of a locator tool, according to an embodiment of the present disclosure;

FIG. **7**D is sectional view schematically illustrating a configuration upon insertion of a stimulation lead via the introduction tool, according to an embodiment of the present disclosure;

FIG. **7**E is sectional view schematically illustrating a configuration of the stimulation lead upon removal of the introduction tool, according to an embodiment of the present disclosure;

FIG. **8**A is a side plan view schematically illustrating a stimulation lead including a distal electrode portion, according to an embodiment of the present disclosure;

FIG. **8**B is a bottom plan view of the stimulation lead of FIG. **8**A including a schematic illustration of a stimulation electrode portion, according to an embodiment of the present disclosure;

FIG. **8**C is a perspective view of the stimulation lead of FIGS. **8**A-**8**B including a schematic illustration of an anchoring mechanism, according to an embodiment of the present disclosure;

FIG. **8**D is a perspective view of a distal portion of a stimulation lead introduction tool, according to an embodiment of the present disclosure;

FIG. **8**E is a sectional view of a distal portion of a stimulation lead introduction tool and a stimulation lead extending therethrough, according to an embodiment of the present disclosure;

FIG. **8**F is partial end view of a distal portion of a stimulation lead having convex-shaped electrode portion, according to an embodiment of the present disclosure;

FIG. **8**G is partial end view of a distal electrode portion of a stimulation lead having a concave-shaped electrode portion, according to an embodiment of the present disclosure;

FIG. **9** is a perspective view of a stimulation lead including an anchoring system, according to an embodiment of the present disclosure;

FIG. **10** is a perspective view of an alternate anchoring system, according to an embodiment of the present disclosure;

FIG. **11** is a sectional view schematically illustrating a method of percutaneous delivery of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **12** is a side plan view of an introduction tool employed in the method associated with FIG. **11**, according to an embodiment of the present disclosure;

FIG. **13** is a bottom plan view of a distal electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **14**A is an enlarged sectional view schematically illustrating a selectively deployable anchoring mechanism of the introduction tool of FIGS. **11-12**, according to an embodiment of the present disclosure;

FIG. **14**B is an enlarged side view schematically illustrating the anchoring mechanism in a deployed state relative to the surrounding tissue, according to an embodiment of the present disclosure;

FIG. **14**C is a sectional view schematically illustrating a distal electrode portion of a stimulation lead secured relative to a nerve via an anchoring mechanism, according to an embodiment of the present disclosure;

FIG. **15** is a perspective view schematically illustrating a bio-absorbable stimulation system prior to absorption, according to an embodiment of the present disclosure;

FIG. **16** is a perspective view schematically illustrating the bio-absorbable stimulation system of FIG. **15** after absorption, according to an embodiment of the present disclosure;

FIG. **17**A is an enlarged side plan view of an electrode portion of the stimulation system of FIGS. **15-16**, according to an embodiment of the present disclosure;

FIG. **17**B is a sectional view as taken along lines **17**B-**17**B of FIG. **16**, according to an embodiment of the present disclosure;

FIG. **18** is a side plan view of a bio-absorbable, stent-electrode stimulation lead, according to an embodiment of the present disclosure;

FIG. **19** is a side plan view schematically illustrating deployment of the stent-electrode stimulation lead of FIG. **18** relative to a nerve, according to an embodiment of the present disclosure;

FIG. **20** is a sectional view schematically illustrating anchoring of an electrode against a nerve after absorption of the bio-absorbable stent portion of the stimulation lead, according to an embodiment of the present disclosure;

FIG. **21** is a side plan view schematically illustrating the electrodes of the stimulation lead against the target nerve after absorption of the bio-absorbable stent portion of the stimulation lead, according to an embodiment of the present disclosure.

FIG. **22** is a perspective view schematically illustrating a bio-absorbable electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **23** is a perspective view schematically illustrating implanted electrodes of the stimulation lead of FIG. **22** prior to absorption, according to an embodiment of the present disclosure;

FIG. **24** is a perspective view schematically illustrating the implanted electrodes of the stimulation lead of FIG. **22** after absorption, according to an embodiment of the present disclosure;

FIG. **25** is a top plan view of an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **26** is a top plan view schematically illustrating a stimulation system as deployed relative to a nerve, including the electrode portion of a stimulation lead and an insulator shield, according to an embodiment of the present disclosure;

FIG. **27** is a sectional view as taken along lines **27-27** of FIG. **26**, according to an embodiment of the present disclosure;

FIG. **28** is a top plan view of an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **29** is a side view schematically illustrating an insulator shield releasably connected, via a coupling mechanism, to an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

FIG. **30** is a sectional view schematically illustrating one aspect of a method of percutaneous access for a stimulation system, according to an embodiment of the present disclosure;

FIG. **31** is a top elevational view schematically illustrating one aspect of the method of percutaneous access, according to an embodiment of the present disclosure; and

FIG. **32** is a sectional view schematically illustrating another aspect of the method of percutaneous access, according to an embodiment of the present disclosure.

DESCRIPTION OF EMBODIMENTS

The following detailed description is merely exemplary in nature and is not intended to limit the present disclosure or the application and uses of the present disclosure. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, or the following detailed description.

Embodiments of the present disclosure provide implantable medical devices, systems, and methods for treating sleep-related disordered breathing, such as but not limited to obstructive sleep apnea. In these methods and systems, stimulation is provided to the hypoglossal nerve (or another target nerve) through a lead system that is delivered percutaneously or delivered using other minimally invasive techniques. In addition, embodiments of the present disclosure include various configurations of the stimulation electrode portion of a stimulation lead.

FIG. **1** is a schematic diagram of an implantable stimulation system that includes a percutaneously placed stimulation electrode, according to an embodiment of the present disclosure. As illustrated in FIG. **1**, an example of an implantable stimulation system **10** according to one embodiment of the present disclosure includes an implantable pulse generator (IPG) **55**, capable of being surgically positioned within a pectoral region of a patient **20**, and a stimulation lead **52** electrically coupled with the IPG **55** via a connector (not shown) positioned within a connection port of the IPG **55**. The lead **52** includes a stimulation electrode portion **65** and extends from the IPG **55** so that the stimulation electrode portion **65** is positioned in contact with a desired nerve, such as the hypoglossal nerve **53** of the patient **10**, to enable stimulation of the nerve **53**, as described below in detail. An exemplary implantable stimulation system in which lead **52** may be utilized, for example, is described in U.S. Pat. No. 6,572,543 to Christopherson et al., and which is incorporated herein by reference in its entirety. In one embodiment, the lead **52** further includes at least one sensor portion **60** (electrically coupled to the IPG **55** and extending from the IPG **55**) positioned in the patient **10** for sensing respiratory effort, such as respiratory pressure.

In some embodiments, the sensor portion **60** detects respiratory patterns (e.g., inspiration, expiration, respiratory pause, etc.) in order to trigger activation of an electrode portion to stimulate a target nerve. Accordingly, with this arrangement, the IPG **55** (FIG. **1**) receives sensor waveforms from the respiratory sensor portion **60**, thereby enabling the IPG **55** to deliver electrical stimulation synchronously with inspiration (or another aspect of the respiratory pattern related to inspiration) according to a therapeutic treatment regimen in accordance with embodiments of the present disclosure. It is also understood that the respiratory sensor portion **60** is powered by the IPG **55** and the IPG **55** also contains internal circuitry to accept and process the impedance signal from the stimulation lead **52**.

In some embodiments, the sensor portion **60** is a pressure sensor. In one aspect, the pressure sensor in this embodiment detects pressure in the thorax of the patient. In another aspect, the sensed pressure could be a combination of thoracic pressure and cardiac pressure (e.g., blood flow). With this configuration, the controller is configured to analyze this pressure sensing information to detect the respiratory patterns of the patient.

In some other embodiments, the respiratory sensor portion **60** comprises a bio-impedance sensor or pair of bio-impedance sensors and can be located in regions other than the pectoral region. In one aspect, such an impedance sensor is configured to sense a bio-impedance signal or pattern whereby the control unit evaluates respiratory patterns within the bio-impedance signal. For bio-impedance sensing, in one embodiment, electric current will be injected through an electrode portion within the body and an electrically conductive portion of a case of the IPG **55** (FIG. **3**A) with the voltage being sensed between two spaced apart stimulation electrode portions (or also between one of the stimulation electrode portions and the electrically conductive portion of the case of IPG **55**) to compute the impedance.

In some embodiments, system **10** also comprises additional sensors to further obtain physiologic data associated with respiratory functions. For example, system **10** may include various sensors (e.g., sensors **67**, **68**, **69** in FIG. **1**) distributed about the chest area for measuring a trans-thoracic bio-impedance signal, an electrocardiogram (ECG) signal, or other respiratory-associated signals.

In some embodiments, the sensing and stimulation system for treating obstructive sleep apnea is a totally implantable system which provides therapeutic solutions for patients diagnosed with obstructive sleep apnea. In other embodiments, one or more components of the system are not implanted in a body of the patient. A few non-limiting examples of such non-implanted components include external sensors (respiration, impedance, etc.), an external processing unit, or an external power source. Of course, it is further understood that the implanted portion(s) of the system provides a communication pathway to enable transmission of data and/or controls signals both to and from the implanted portions of the system relative to the external portions of the system. The communication pathway includes a radiofrequency (RF) telemetry link or other wireless communication protocols.

Whether partially implantable or totally implantable, the system is designed to stimulate the hypoglossal nerve during inspiration to thereby prevent obstructions or occlusions in the upper airway during sleep. In one embodiment, the implantable system comprises an implantable pulse generator (IPG), a peripheral nerve cuff stimulation lead, and a pressure sensing lead.

FIG. **2** is a block diagram schematically illustrating an implantable stimulation system **100**, according to one embodiment of the present disclosure. In one embodiment, system **100** comprises at least substantially the same features and attributes as system **10** of FIG. **1**. As illustrated in FIG. **2**, system **100** includes a sensing module **102**, a stimulation module **104**, a therapy module **106**, and a patient management module **108**. In one embodiment, the IPG **109** of therapy module **106** comprises at least substantially the same features and attributes as IPG **55** of FIG.

Via an array of parameters, the sensing module **102** receives and tracks signals from various physiologic sensors (such as a pressure sensor, blood oxygenation sensor, acoustic sensor, electrocardiogram (ECG) sensor, or impedance sensor) in order to determine a respiratory state of a patient, whether or not the patient is asleep or awake, and other respiratory-associated indicators, etc. Such respiratory detection may be received from either a single sensor or any multiple of sensors, or combination of various physiologic sensors which may provide a more reliable and accurate signal.

For example, in one embodiment, the sensing module **102** comprises a sensing monitor **120**, as illustrated in FIG. **3**. The sensing monitor **120** includes a body parameter **130**, which includes at least one of a position-sensing component **132** or a motion-sensing component **134**. In one embodiment, the motion-sensing component **134** tracks sensing of "seismic" activity (via an accelerometer or a piezoelectric transducer) that is indicative of walking, body motion, talking, etc. In another embodiment, the position-sensing component **132** tracks sensing of a body position or posture via an accelerometer or other transducer. In some embodiments, body parameter **130** utilizes signals from both the position-sensing component **132** and the motion-sensing component **134**.

In some embodiments, sensing monitor **120** additionally comprises one or more of the following parameters: an ECG parameter **136**; a time parameter **138**; a bio-impedance parameter **140**; a pressure parameter **142**; and a blood oxygen parameter **144**. In one aspect, the pressure parameter **142** includes a respiratory pressure component **143**. In one aspect, the time parameter **142** tracks time generally (e.g. time intervals, elapsed time, etc.) while in other aspects, the time parameter **142** tracks the time of day in addition to or instead of the general time parameters. In another aspect, the time parameter **142** can be used to activate or deactivate a therapy regimen according to a time of day.

It is also understood that system **100** (FIG. **2**) would include, or be connected to, the analogous physiologic sensor (e.g., LED-type or optical tissue perfusion oxygen saturation) implanted within or attached to the body of the patient to provide data to each one of their respective parameters (e.g., blood oxygenation parameter **144**) of the sensing monitor **120**. In some embodiments, sensing monitor **120** also includes a target nerve parameter **146** which represents physiologic data regarding the activity of a nerve to be stimulated, such as the hypoglossal nerve, including specification of the trunk and/or one or more branches of the hypoglossal nerve. In yet other embodiments, sensing monitor **120** also includes an acoustic sensing parameter **147** which represents physiologic data from respiratory airflow or cardiac activity that is sensed acoustically and that is indicative of respiratory effort.

In further reference to FIG. **2**, therapy manager **106** of system **100** is configured to automatically control initiation, termination, and/or adjustment of a sleep apnea therapy, in accordance with the principles of the present disclosure. Therapy manager **106** also tracks and applies various treatment parameters, such as an amplitude, pulse width, electrode polarity, duration, and/or frequency of a neuro-stimulation signal, in accordance with a treatment protocol programmed into the therapy manager **106**.

In one embodiment, therapy manager **106** comprises one or more processing units and associated memories configured to generate control signals directing the operation of system **100**, including at least sensing module **102**, therapy manager **106**, stimulation module **104**, and patient management module **108**. In particular, in response to or based upon commands received via an input and/or instructions contained in the memory associated with the controller in response to physiologic data gathered via the sensing module **102**, therapy manager **106** generates control signals directing operation of stimulation module **104** to selectively control stimulation of a target nerve, such as the hypoglossal nerve, to restore airway patency and thereby reduce or eliminate apnea events.

With this in mind, therapy manager **106** acts to synthesize respiratory information, to determine suitable stimulation parameters based on that respiratory information, and to direct electrical stimulation to the target nerve. While any number of physiologic parameters can be used with varying success to detect an apnea, in one embodiment of the present disclosure, the sensing module **102** detects apneas via a thoracic bio-impedance parameter. In particular, a measurement of thoracic impedance is used to track the relative amplitude of the respiratory waveform. Physiologically speaking, the bio-impedance of the lungs varies as the lungs fill and empty with air. Accordingly, thoracic impedance increases during inspiration and decreases during expiration. In another aspect, a varying respiratory drive will also cause the amplitude of the bio-impedance to vary, with a larger respiratory drive increasing the signal amplitude of the bio-impedance.

Upon obtaining the bio-impedance signal, the bio-impedance signal is further processed to identify an average peak amplitude over time. An apnea is detected by further identifying cyclic amplitude variations that occur for a duration substantially similar to the already known duration of a typical apnea event.

For purposes of this application, the term "processing unit" shall mean a presently developed or future developed processing unit that executes sequences of instructions contained in a memory. Execution of the sequences of instructions causes the processing unit to perform steps such as generating control signals. The instructions may be loaded in a random access memory (RAM) for execution by the processing unit from a read only memory (ROM), a mass storage device, or some other persistent storage, as represented by a memory associated with the controller. In other embodiments, hard wired circuitry may be used in place of or in combination with software instructions to implement the functions described. For example, the controller may be embodied as part of one or more application-specific integrated circuits (ASICs). Unless otherwise specifically noted, the controller is not limited to any specific combination of hardware circuitry and software, nor limited to any particular source for the instructions executed by the processing unit.

In general terms, the stimulation module **104** of system **100** is configured to generate and apply a neuro-stimulation signal via electrode(s) (such as stimulation electrode(s) **65**) according to a treatment regimen programmed by a physician and/or in cooperation with therapy manager **106**.

In general terms, the patient management module **108** is configured to facilitate communication to and from the IPG **109** in a manner familiar to those skilled in the art. Accordingly, the patient management module **108** is configured to report activities of the IPG **109** (including sensed physiologic data, stimulation history, number of apneas detected, etc.) and is configured to receive initial or further programming of the IPG **109** from an external source, such as a patient programmer, clinician programmer, etc.

In accordance with at least one embodiment of the present disclosure, a stimulation site locator tool **200** of a percutaneous delivery system **201** is schematically illustrated in the plan view of FIG. **4**. In general terms, the site locator tool **200** is configured to facilitate identifying a target or optimal stimulation site and/or a point of penetration to perform a percutaneous delivery of a stimulation lead near the target stimulation site. As shown in FIG. **4**, site locator tool **200** includes a needle **210** extending from a handle **212**. The needle **210** includes a distal tip **214**, needle body **216**, and a series of depth markers **218** extending along the needle body **216**. The needle **210** extends proximally from the distal tip **214** and through handle **212**, terminating at proximal end **219**. At proximal end **219**, a connection port **236** provides releasable electrical connection between the needle **210** and a stimulation monitor (as later described in more detail), which provides an electrical stimulation signal at distal tip **214**.

Referring again to FIG. **4**, in one aspect, the needle body **216** includes a dielectric coating on its outer surface while a conductive surface of the distal tip **214** is exposed to allow electrical conductivity between the distal tip **214** and the tissue within the body. The depth markers **218** are visible to the eye and may in some embodiments, be formed of a material that is readily visible through radiographic and/or ultrasound visualization techniques, as later described in more detail.

Moreover, it is understood that various surgical visualization techniques can be used in association with the embodiments of the present disclosure to assist in determining the location of the site locator tool **200**, the stimulation electrode portion, and other components involved in percutaneous delivery of the stimulation lead.

By inserting the site locator tool **200** percutaneously at various locations near or adjacent to the hypoglossal nerve (in cooperation with a stimulation monitor) the path of the hypoglossal nerve is identified based on the type and magnitude of neurogenic responses, such as neuromuscular responses, observed upon application of the test stimulation signal at those various test locations. In this way, those test locations that exhibit a neuromuscular response indicative of a quality nerve capture are used to identify the optimal or target site to place a stimulation electrode portion of a stimulation lead. These observed responses are also used to identify a skin insertion point at which the percutaneous access will be initiated.

In some embodiments, the neuro-stimulation signal is applied at a single stimulation site along the hypoglossal nerve as illustrated in FIG. **1** (see stimulation electrode portion **65**). However, in other embodiments, the neuro-stimulation signal of a sleep apnea therapy is applied from two or more of multiple locations spaced longitudinally along the hypoglossal nerve. In such an arrangement, the separate, spaced apart stimulation electrode portions can be activated simultaneously or activated at different times. With this in mind, it is understood that the percutaneous access method can be applied to locate more than one site along the hypoglossal nerve to identify placement of several different stimulation electrode portions.

In further reference to FIG. **4**, in cooperation with the site locator tool **200** a stimulation monitor, such as a nerve integrity monitor **250** (a stand alone monitor or a monitor integrated into a sleep apnea physician programmer **108**, such as programmer **108** in FIG. **2**), is connected to the site locator tool **200** via connector **237**. The stimulation monitor is used to aide the physician in determining proper electrode placement via stimulation applied via the site locator tool

200. In one embodiment, an IPG **55** (FIG. **1**) or IPG **109** (FIG. **2**) can be used as the stimulation monitor. In some embodiments, the stand-alone nerve integrity monitor **250** comprises at least substantially the same features and attributes as the nerve integrity monitor described in U.S. Pat. No. 6,334,068, entitled INTRAOPERATIVE NEURO-ELECTROPHYSIOLOGICAL MONITOR, issued on Dec. 25, 2001, and which is hereby incorporated by reference in its entirety. In other embodiments, other nerve integrity monitors or an equivalent array of instruments (e.g., a stimulation probe and electromyography system) are used to apply the stimulation signal and evaluate the response of the muscle innervated by the target nerve.

As shown in FIG. **4**, in some embodiments nerve integrity monitor **250** comprises stimulation module **252** and a response module **254** that includes electromyography monitoring electronics (EMG) **256**. In addition, FIG. **4** further illustrates a response evaluation array **275**, according to one embodiment of the present disclosure. The response evaluation array **275** provides one or more mechanisms to evaluate the effectiveness of a target site for stimulating a target nerve and to identify an entry point for percutaneous delivery of the stimulation electrode portion. In one embodiment, upon stimulation applied at a potential target site, the response array **275** includes: (1) observing or measuring the extent and location (an extension of the base of the tongue is preferred over extension of the tip) of tongue protrusion **278** (indicated by arrow P); (2) observing or measuring the extent of increased cross-sectional area (indicated by arrow W) of an upper respiratory airway **277**, with the observation/measurement being performed via endoscopy, ultrasound, or other visualization techniques; and/or (3) measuring the extent of an EMG response **280** (measured via EMG electronics **256** of monitor **250**) of one or more muscles.

Accordingly, with this in mind, monitor **250** and one or more aspects of the response array **275** are used to evaluate the positioning of site locator tool **200** relative to a potential stimulation site on a target nerve. In one aspect, a repetitive stimulation pattern is applied from the stimulation module **252** of nerve integrity monitor **250** to the distal tip **214** of site locator tool **200**, as the site locator tool **200** is percutaneously inserted into various locations adjacent to the target nerve and into the target nerve. In some embodiments, the applied stimulation pattern is a 1 second burst of stimulation every 3 seconds, a ramping stimulation pattern, and/or a physician controlled burst. In another aspect, electromyography (EMG) monitoring electronics **256** of the nerve integrity monitor **250** enables measuring a muscle response to the nerve stimulation applied during the iterative percutaneous insertion of the site locator tool **200**. Accordingly, as further shown in FIG. **4**, fine wire electrodes **282** (or similar) are connected in electrical communication with EMG electronics **256** of the nerve integrity monitor **250** and are used to continuously monitor the muscle activity in response to the stimulation patterns applied via site locator tool **200**. Using this arrangement, this closed loop feedback will allow the physician to obtain real-time feedback of a position of the site locator tool **200** (relative to the hypoglossal nerve) and feedback regarding the expected ability of a percutaneously implanted electrode lead to capture the target nerve.

In one embodiment of the present disclosure, as illustrated in FIG. **5**, a method **300** of treating apnea includes identifying an optimal site to locate stimulation electrode portion **65** (FIG. **1**) along a length of the hypoglossal nerve that will result in a desired stimulation of the hypoglossal nerve and treatment of sleep apnea. In particular, as illustrated at **302** in FIG. **5**, the site locator tool **200** is inserted percutaneously (through the skin toward the target nerve) into various test stimulation sites at or around the hypoglossal nerve. For example, as further shown in the diagram **400** of FIG. **7A**, needle **210** extends through percutaneous access path **408** such that distal tip **214** becomes electrically coupled relative to nerve **410** at one of several potential stimulation sites (e.g., A, B, C) with proximal handle **212** external to skin surface **402**. Via surgical navigation techniques, the graduation markers **218** enable measuring a depth of insertion through skin **402** and other subcutaneous tissues **404**, **405** surrounding nerve **410**. While FIGS. **4** and **7A** illustrate just a few such markers **218** for illustrative purposes, it will be understood that markers **218** would extend along a length or substantial length of needle **210** and that the spacing of such markers **218** may vary from that shown in FIGS. **4** and **7A**. It will be understood that various components of tool **200** and the surrounding tissues are enlarged and/or minimized for illustrative purposes.

At each test site, a pre-determined profile of electrical stimuli is applied to identify one or more optimal or preferred target sites on the hypoglossal nerve. As illustrated at **304** in FIG. **5**, the optimal or preferred target site are identified from among the test sites based observing or measuring at least: (1) a degree of tongue protrusion; (2) the size of cross-sectional area of the upper airway; (3) a best EMG response indicative of maintaining airway patency; (4) a lack of response from non-target muscles; and/or (5) a twitch from the tongue muscle and/or laryngeal muscle. In one aspect, an optimal or preferred target stimulation site is correlated with the greatest impact on maintaining airway patency during inspiration. After identifying a target site, method **300** includes identifying a percutaneous access pathway to the target site. In one aspect, this identification includes identifying a skin entry site (such as D, E, F, or G), which may or may not be directly above the target stimulation site on the hypoglossal nerve. Finally, it is understood that these steps **302-306** can be repeated iteratively, as necessary, until all the optimal stimulation locations along the target nerve are identified.

In one aspect, in evaluating various test stimulation sites, it will be understood that the magnitude of the measured response will be indicative how close the site locator tool **200** is to the hypoglossal nerve and/or which part of the hypoglossal nerve is being stimulated. For example, the distance between the site locator tool **200** and the hypoglossal nerve and the strength of the measured response is expressed in decreasing exponential relationship. In other words, as the distance away from the hypoglossal nerve increases, there is an exponential decrease in the magnitude of the measured response. In one aspect, the distance refers to a distance measured in three dimensions relative to the path of the hypoglossal nerve, as any given test site will involve: a lateral distance extending generally perpendicular relative to a longitudinal axis of the target nerve; (2) a vertical distance relative to the target nerve; and (3) a longitudinal distance extending generally parallel relative to a longitudinal axis of the target nerve. With this in mind, it is understood that as multiple potential sites are tested, a pattern is identified that highlights the best or optimal stimulation site(s) from among the test sites. In addition, other surgical navigation techniques can be used in cooperation with the application of the test stimulus to further pinpoint the optimal/preferred stimulation sites via visualizing the site locator tool **200** within the target anatomical environment at the time that the responses are measured.

In some embodiments, in evaluating multiple potential stimulation sites along the hypoglossal nerve, at each potential stimulation site the method **300** applies the pre-determined electrical stimuli as a stimulation signal with differing values for each signal parameter (e.g., pulse width, electrode polarity, frequency, duration, and amplitude) to determine which combination of values yields the best impact of the stimulation signal upon the target nerve at a potential site. In this way, each potential site is evaluated under conditions in which the stimulation signal would actually be applied were that potential site chosen as an optimal site for stimulation. In one embodiment, this determination of an optimal stimulation site via evaluating each of the stimulation parameters employs therapy module **106** (including IPG **109**) in cooperation with stimulation module **104**, a site locator tool **200**, and patient programming module **108**, as previously described in association with FIGS. **1**-**4**.

In one aspect, an optimal stimulation site identified via the site locator tool **200** is preserved to allow an accurate delivery of the stimulation electrode portion of the stimulation lead to that site. Accordingly, in some embodiments, while maintaining needle **210** in its inserted position in the optimal site along the hypoglossal nerve, handle **212** is removed from needle body **216** while maintaining the distal tip **214** in a coupled relationship to nerve **410**, and then a lead introduction tool Leis slidably advanced over the proximal portion **219** of needle **210** of site locator tool **200** to produce configuration shown in FIG. **7**B, as will be further described later.

In general terms, a stimulation lead is inserted percutaneously to result in a distal portion of the stimulation lead being closely adjacent to a target stimulation site of a nerve. In some embodiments, an introducing mechanism is used to initiate and develop a percutaneous access pathway to the target stimulation site and facilitates introduction of the stimulation lead therethrough. While various different shapes and forms of lead introduction tools can be used, FIG. **6**A illustrates one exemplary embodiment of a lead introduction tool **350**. As shown in FIG. **6**A, lead introduction tool **350** includes a cannula **360** extending through and supported by handle **362**. Cannula **360** includes a curved distal portion **375** with a body portion **366** extending proximally from distal portion **375** to a proximal portion **369** within handle **362**. In one aspect, cannula **360** includes a series of graduation depth markers **368** to permit measurement of the desired depth of insertion. While FIGS. **6**A and **7**B illustrate just a few such markers **368** for illustrative purposes, it will be understood that markers **368** would extend along a length or substantial length of cannula **360** and that the spacing of such markers **368** may vary from that shown in FIGS. **6**A and **7**B. In some embodiments, at least some of the depth markers **368** are also formed of a radiopaque material to enable visualization under fluoroscopy or other visualization techniques to ensure a proper orientation, position, and placement of the cannula **360** relative to a target nerve and/or other tissues, structures, etc. It also will be understood that at least some conductive portions of cannula **360**, needle **210** will be visualized under fluoroscopy or other visualization techniques to further aid ensuring proper placement, orientation, and/or position of those respective elements.

As shown in the sectional view of FIG. **6**B, cannula **360** defines a lumen **370** that extends throughout body portion **366**. In general terms, cannula **360** is a generally tubular structure with electrically conductive properties. Accordingly, as shown in FIG. **6**B, in one aspect, body portion **366** has a dielectric or insulative coating **367** on its outer surface while distal tip **364** of cannula **360** omits a dielectric coating.

In one embodiment, distal tip **364** includes an end opening **390** sized and shaped to facilitate passage of a stimulation lead therethrough. Moreover, curved distal portion **372** is formed of a generally resilient, flexible material. Accordingly, upon slidably advancing cannula body **366** over a pre-placed site locator tool **200**, as illustrated in FIGS. **4** and **7**A, curved distal portion **372** assumes a generally straight shape to aid its insertion percutaneously through skin **402** and tissues **404**, **405** at an angle generally perpendicular to the hypoglossal nerve, as shown in FIG. **7**B. In addition, in this position, the proximal portion and/or handle **362** of tool **350** remains external to skin surface **402**. It will be understood that in some embodiments, in the absence of site locator tool **200**, a stiffener or stylet, as known to those skilled in the art, can be used to maintain the cannula body **366** in a straight configuration during its insertion percutaneously. One generally example of such stylets is described and illustrated in Buckberg U.S. Pat. No. 5,226,427, which is hereby incorporated by reference in its entirety.

In its straightened shape, cannula **310** has a shape substantially similar to that shown for tool **380** that is later described in association with FIG. **6**C. Referring again to FIG. **6**A, once the distal tip **364** is located at a desired depth, the locator tool **200** (or other stiffener) is removed causing the curved distal portion **372** to relax and resume its generally curved shape, as shown in FIG. **7**C. This relaxation, in turn, orients distal end opening **378** to be generally parallel to the hypoglossal nerve **410** as shown in FIG. **7**C, thereby assuming a position suitable to direct a stimulation lead to be slidably advanced along the hypoglossal nerve to a desired stimulation site. In some embodiments, upon such relaxation, the distal end opening **378** is oriented at a generally obtuse angle relative to the generally straight proximal portion of the cannula **310**.

In some embodiments, as will be understood by those skilled in the art, when identifying the optimal stimulation site (A) from among multiple potential sites (e.g. A, B, C, etc.), the site locator tool **200** would also be used to identify a corresponding entry point (e.g., D, E, F, G, etc.) of the lead introduction tool that is distal or proximal to the optimal stimulation site (e.g., A), as illustrated in FIGS. **7**A-**7**E. In one embodiment, the spacing (along an axis generally parallel to the hypoglossal nerve) between the entry point at the skin surface (e.g., E) and the optimal stimulation site (A) on the hypoglossal nerve is substantially equal to the distance (D**1**) that distal end opening **378** extends from the generally perpendicular (relative to the hypoglossal nerve) orientation of cannula body portion **366** when inserted.

In another embodiment, the spacing between the skin entry point and the optimal stimulation site is configured to further account for the length (represented by D**2** in FIG. **6**A) of the stimulation lead (including the electrode portion as represented by dashed lines **395**) that would extend out of end opening **378** to deliver the electrode portion of the stimulation lead at the target stimulation site. This arrangement further insures that the final placement of the electrode portion of the stimulation lead accurately corresponds to the previously identified optimal or target stimulation site (e.g. A in FIGS. **7**A-**7**E). However, it will be further understood that in some embodiments, the distal end of the stimulation lead is positioned to extend beyond the target stimulation site marked at distance D2 to ensure that the target stimulation site remains generally centered along the length of the electrode portion (e.g., electrode array **442** of portion **440** as later described in relation to FIG. **8**A-**8**C) of the stimulation lead. In such embodiments, the distance D2 corresponds to a length no more than a length of the electrode portion and likely less than (e.g. about one-quarter, one-half, or three-quarters) a length of the electrode portion (e.g. electrode array **442** of portion **440** in FIGS. **8**A-**8**C).

Accordingly, in this embodiment the total spacing (along an axis generally parallel to a longitudinal axis of the hypoglossal nerve in this region) between the skin entry point and the optimal stimulation site would be the combination of the distances D**1** and D**2**. With this in mind, in one embodiment, after the optimal stimulation site (e.g. A from among A, B, C, etc.) is identified via the site locator tool **200**, the site locator tool **200** is used to trace the path of the hypoglossal nerve (or other suitable anatomical landmark) to identify a skin entry point (e.g. E in FIG. **7**A-**7**B) for the lead introduction tool **350** that spaced apart from the optimal stimulation site (e.g. A in FIGS. **7**A-**7**B) by a distance of D**1** plus D**2**.

In one aspect, tracking these distances D**1** and D**2** greatly enhances the introduction of the stimulation lead to arrive at the optimal stimulation site because of the relative absence of significant anatomical structures (e.g., bone canals, protuberances, etc.) in the region of the hypoglossal nerve that is to be stimulated.

In another embodiment, a lead introduction tool **380** (shown in FIG. **6**A) includes substantially the same features and attributes as lead introduction tool **350** of FIGS. **6**A-**6**B, except for including a straight distal portion **382** with a side opening **390** instead of the curved distal portion **372** and end opening **378** shown in FIG. **6**A. Accordingly, in this embodiment, straight distal portion **382** includes the side opening **390** sized and shaped to facilitate passage of a distal portion of a stimulation lead therethrough. In one aspect, opening **390** is configured as a side-directed, non-coring opening for lumen **370**. With this arrangement, upon insertion percutaneously, the cannula body **360** of tool **380** is oriented generally perpendicular relative to the skin and relative to the hypoglossal nerve, with the distal side opening **390** enabling a stimulation lead to exit cannula body **360** in a path extending at a generally obtuse angle relative to the orientation of body **360** (as it percutaneously extends through a skin surface and tissues) and generally parallel to the hypoglossal nerve to be advanced generally parallel to the hypoglossal nerve.

When using lead introduction tool **380**, the distance D**1** shown in FIG. **6**A and FIGS. **7**C-**7**E is generally not tracked because of the straight shape of distal portion **382** (including tip **384**) and because the lead introduction tool **380** is oriented generally perpendicular to the hypoglossal nerve over the optimal stimulation site. However, in one aspect, one can optionally account for the length of the electrode portion of a stimulation lead as it would extend generally outward and away from the distal tip **384** through opening **390** (and generally perpendicular to a longitudinal axis of the cannula body **360**). Accordingly, in the embodiment of lead introduction tool **380**, in addition to identifying the optimal stimulation site (e.g. A in FIGS. **7**A-**7**E) with the site locator tool **200**, the operator would also identify a skin entry point (e.g. G in FIG. **7**C) that is spaced by the distance D**2** from the optimal stimulation site. The distance D**2** generally corresponds to the length of the stimulation lead (including the electrode portion) that would extend out of distal side opening **390** to deliver the electrode portion of the stimulation lead at the target stimulation site. In this way, the operator insures that the electrode portion of the stimulation lead is accurately delivered to the identified target stimulation site (e.g. A). As noted previously, the distance D**2** would have a length no more than, and likely less than, a length of the electrode portion (such as electrode array **442** in FIG. **8**B) to ensure centering the electrode portion relative to the target stimulation site.

In some embodiments, the stimulation lead (e.g., stimulation lead **430** as will be described in association with at least FIGS. **8**A-**8**E) is configured to be cooperable with a removably attachable stylet to facilitate advancing the stimulation lead through cannula **380** and through the tissue surrounding the target stimulation site. In particular, as the distal portion of the stimulation lead exits the distal side opening **410**, the distal portion **436** will have to be advanced via tunneling through the surrounding tissue. With this in mind, the stylet will provide rigidity as the stimulation lead is tunneled to the target stimulation site and once the stimulation lead is properly positioned, the stylet is removed from its connection to the stimulation lead. Moreover, in some embodiments, this stylet is also used to selectively deploy an anchoring mechanism associated with the electrode portion of the stimulation lead.

In some embodiments, the cannula of lead introduction tool **350** or **380** is generally non-conductive and the conductive elements of the site locator tool **200** and/or of the stiffener are used as an electrically conductive pathway to confirm the location of the target stimulation site and/or the location of the skin entry point spaced from the target stimulation site.

In some embodiments, other types of introducing mechanisms are used to establish a percutaneous access pathway for a stimulation lead. For example, one introducing mechanism includes a guide wire and a needle having a cannula and a stylet. With this arrangement, the needle cannula is percutaneously inserted to establish a percutaneous pathway with aid from the stylet to steer, guide, and/or stiffen the needle cannula. After a path is established by the combination of the cannula and stylet, the stylet is removed. With the cannula still in place, a guide wire is inserted into a proximal portion of the cannula and advanced through the cannula until a distal portion of the guide wire is adjacent the target stimulation site. Next, with the guide wire still in place, the cannula portion of the needle is removed proximally over the guide wire, leaving just the guide wire in place. Using known techniques, a stimulation lead is releasably coupled to the guide wire and advanced, via the guide wire, through the established percutaneous access pathway until an electrode portion of the stimulation lead is adjacent the target stimulation site. With the stimulation lead remaining in place, the guide wire is then removed. Finally, the stimulation lead is anchored to maintain the electrode portion in an electrically coupled relationship with the target stimulation site of the nerve.

While various different shapes and forms of leads can be used in the methods and systems of the present disclosure, FIGS. **8**A-**8**C illustrate one exemplary embodiment of a stimulation lead **430** is that is configured to be deployed percutaneously. In one embodiment, the stimulation lead **430** is delivered via the tools **200**, **350**, **380** (as previously described in association with FIGS. **4**-**7**) while in other embodiments, the stimulation lead **430** is delivered via other minimally invasive delivery techniques. Various aspects of the delivery of stimulation lead **430** will be described herein in further detail.

As shown in FIGS. **8**A-**8**C, stimulation lead **430** includes a front side **432** and a back side **434** with the lead **430** extending between a distal portion **436** and a proximal portion **438**.

At distal portion **436**, the front side **432** supports an electrode portion **440** including a first array **442** of electrodes **444**. In general terms, substantially the entire length of the electrode portion **440** comprises a generally flat surface and when the back side **434** also forms a generally flat surface, then the entire distal portion **436** defining the electrode portion **440** comprises a generally flat or planar member (with the exception of the to-be-described protrusions **464** on back side **434**).

This generally flat or planar configuration of distal portion **436** (including stimulation electrode portion **440**) provides a low profile topography, thereby facilitating its advancement through the tissue surrounding the hypoglossal nerve. In addition, by having at least a generally flat surface of the front side **432** of distal portion **436**, a much closer and effective interface between the stimulation electrode portion **440** and the surface of the hypoglossal nerve can be achieved. However, in some other embodiments, the front side **432** of the distal portion **436** is not generally flat, but has at least some curved portion or undulating portion. In one example, as illustrated in FIG. **8**F, the curved portion of the front side **432** of the distal portion **436** forms a generally concave shape configured to accentuate the extent to which the electrode portion **440** reciprocally conforms to the generally arcuate shape of the outer surface of the hypoglossal nerve. In another example, as illustrated in FIG. **8**G, the front side **432** of the distal portion **436** forms a generally convex shape. In one aspect, this generally convex shape is configured to accentuate slidable passage of the distal portion through the tissue surrounding the hypoglossal nerve to arrive at the optimal stimulation site

Likewise, in some embodiments, the back side **434** of the distal portion **436** is not generally flat, but has at least some curved portion which can be concave or convex. In one aspect, a generally convex shape on the back side **436** is configured to accentuate slidable passage of the distal portion through the tissue surrounding the hypoglossal nerve to arrive at the target stimulation site.

In another aspect, because the front side **432** carries electrode portion **440**, the back side **434** of the distal portion **436** is generally made or coated with an electrically insulative material. With this arrangement, back side **434** effectively acts as a shield to prevent the stimulation signal from affecting the sensory nerves and skin overlying the stimulation site.

In another aspect, at proximal portion **438** of stimulation lead **430**, a second array **450** of electrodes **452** is formed on both the front side **432** and the back side **434** of stimulation lead **430**. The first array **442** of electrodes **444** are electrically connected to the second array **450** of electrodes **452** with the second array **450** of electrodes **452** configured to provide electrical connection to the IPG (**55** in FIG. **1** or **109** in FIG. **2**). Via control from the IPG **55**, each electrode **444** of stimulation electrode portion **440** is independently programmable to apply a stimulation signal that has a selectively controllable polarity, amplitude, frequency, pulse width, and/or duration.

In one embodiment, the first array **442** of electrodes **444** includes a lateral component (i.e., extending along a width W**1**) or a longitudinal component (i.e., extending along a length L**1**) of at least three electrodes in a guarded cathode electrode polarity arrangement. This guarded cathode electrode polarity arrangement hyperpolarizes tissues near the hypoglossal nerve while providing for complete depolarization of the volume of the hypoglossal nerve adjacent the electrode portion **440** of the stimulation lead **430**. However, as shown in FIG. **8**B, in some embodiments, the first array **442** includes a multitude of electrodes **444** (substantially greater than three) extending along the width and along the length of the electrode portion **440**. This arrangement permits selection of different combinations of electrodes **444** from among the first array **442**, thereby optimizing the stimulation of the hypoglossal nerve via an optimal combination of electrodes **444** within the first array **442**. Moreover, in some embodiments, one or more of the electrodes **444** are varied in shape and/or pitch, or varied by staggering of the rows of electrodes **444**.

In some embodiments, with the assumption that a diameter of the target nerve in the region of the target stimulation site is about 3 millimeters, the electrode portion **440** will have a width (W**1** in FIG. **8**B) of at least about 5 millimeters. Accordingly, in these embodiments, the width (W**1**) of the electrode portion **440** is at least substantially equal to or substantially greater than the diameter of the target nerve in the region of the target stimulation site. This relationship insures that the electrical stimulation signal (for treating sleep apnea) will affect the full cross-section of the nerve so that substantially all the axons of the target nerve will potentially be activated (depending upon the parameters of the applied stimulation signal).

A body portion **437** extends between the electrode portion **440** (at the distal portion **436**) and the proximal portion **438**. With the exception of electrodes **444**, the body portion **437** is a generally insulative member devoid of electrodes on the front side **432** and back side **434**. It is understood, of course, that wires extend through an interior of the body portion **437** to connect electrodes **444** to the IPG (**55** in FIG. **1** or **109** in FIG. **2**). In general terms, the body portion **437** has a length sufficient to extend from the electrode portion **440** to the IPG **55** (FIG. **1**).

In some embodiments, the distal portion **436** of stimulation lead **430** includes an anchoring mechanism **462** located on back side **434**, i.e. on an opposite side relative to the stimulation electrode portion **440**. In one aspect, the anchoring mechanism **462** provides a cuff-less arrangement to secure the electrode portion **440** in close proximity to the nerve with the anchoring mechanism being disposed on an opposite side of the electrode portion **440** so that the anchoring mechanism **462** faces away from the nerve. This arrangement secures the electrode portion independently of the nerve and in a desired position relative to the nerve without placing any pressure or other mechanical effects on the nerve that might otherwise be used to secure an electrode relative to a nerve.

In one aspect, the anchoring mechanism **462** includes at least one array of protrusions **464**. In one embodiment, the protrusions **464** are flaps formed of a resilient material while in other embodiments, the protrusions **464** are barbs, prongs, or other anchoring components. In some of these embodiments, the protrusions are sized and shaped to induce fibrotic growth at and near the protrusions to cause further anchoring of the distal portion **436** of the stimulation lead **430**. In one aspect, within about one month, the protrusions **464** become ingrown with fibrotic tissue. Accordingly, while the protrusions **464** act to provide some long-term stability to the position of stimulation lead **430** within the body, one purpose of the protrusions **464** is to provide such stability for at least about one month, which generally corresponds to the amount of time for fibrotic tissue growth to effect a more permanent, long term stabilization of electrode portion **440** at the target site within the body.

In one aspect, the protrusions **464** extend generally outward at an angle (e.g., 30, 45, 60 degrees) from a surface of the back side **434** of the distal portion **436** of the stimulation lead **430**. As shown in FIGS. **8**A and **8**B, in some embodiments, at least one pair of the protrusions **464** are provided in a divergent orientation which enhances the stability of the stimulation lead **430** by reducing the likelihood of the stimulation lead **430** from migrating away from its placed location. In particular, once implanted, the divergent orientation of the protrusions **464** enhance maintaining the electrode portion **440** of the stimulation lead **430** in its target location regardless of the direction of applied forces on the stimulation lead. In one aspect, the protrusions **464** have a length and width configured to engage or integrate with the tissues surrounding the hypoglossal nerve. However, in another aspect, the protrusions **464** form a generally tab-like structure made of a flexible polymer that can collapse upon application of a sufficiently high force, thereby enabling adjustment of the position of the electrode portion **440** of the stimulation lead **430** and/or removal of the stimulation lead **430**.

In some embodiments, the protrusions **464** are sized and shaped to facilitate their disengagement from the surrounding tissues (via the use of a tool) to enable removal of the electrode portion **440** of the stimulation lead **430** from its implanted location adjacent the hypoglossal nerve. Such removal would take place in the event that a trial treatment plan was ineffective or in the event that the stimulation lead **430** was malfunctioning.

However, in the event that only some of the electrodes **444** were malfunctioning, the stimulation lead **430** need not be removed because the IPG **55** of FIG. **1** (or IPG **109** in FIG. **2**) can be used to activate a different set of electrodes **444** within the first array **442** to produce a new combination of electrodes **444** arranged to apply a therapeutic regimen for treating sleep apnea. Moreover, an adjustment of the stimulation parameters (e.g., amplitude, pulse width, frequency, duration, and electrode polarity) via the IPG **55**, **109** can compensate for the different position of the electrodes in the new combination of activated electrodes **444** for applying the stimulation signal. In this embodiment, the many varied positions of the electrodes **444** both along the length of the distal portion **436** of the electrode portion **440** of the lead **430** and transversely across the distal portion **436** enables precise activation of selective groups of electrodes **444** (at their various spaced apart locations) to produce an effective stimulation signal. Likewise, in the event that some inadvertent migration of the stimulation lead **430** occurs distally or proximally relative to the optimal stimulation site after the stimulation lead **430** has been considered to be properly placed, then the IPG **55** (or IPG **109** in FIG. **2**) is used to activate a different set of electrodes **444** of the first array **442** to achieve a stimulation signal that compensates for the migration to maintain a proper stimulation signal at the target stimulation site.

The stimulation lead **430** is configured to balance various parameters including optimal electrode orientation, patient comfort, anchor strength, preventing migration of the lead, and providing for removability of the lead, as well as facilitating subcutaneous tunneling of the stimulation lead **430** to the site of the IPG. As such, this stimulation lead **430** provides several advantageous features, including providing for stimulation of the entire cross-sectional volume of the hypoglossal nerve volume in a manner comparable with cuff electrodes. Moreover, by facing the electrodes **444** away from the skin and by backing the electrodes **444** with an insulative layer (body portion **437**), the stimulation lead **430** minimizes stimulation of nearby sensory nerves. In addition, by having an array **442** of multiple electrodes **444** that are independently programmable or controllable relative to each other via operation of IPG **55**, the therapy can be adjusted in a non-invasive manner in the event that the stimulation lead **430** migrates from its original placement. In other words, the stimulation can be shifted from one combination of electrodes **444** in the array **442** to a different combination of electrodes **444** in the array **442** to account for the shift in the overall position of the electrode portion **440** of the stimulation lead **430** relative to the hypoglossal nerve. Of course, it will be understood that different combinations of electrodes **444** can be activated simply to achieve a different therapy regimen, even in the absence of migration or malfunction of electrode array **442**.

In use, the stimulation lead **430** is delivered percutaneously via feeding the distal portion **436** into a proximal portion **369** of the cannula **360** of lead introduction tool **350** or **380** and slidably advancing the distal portion **436** therethrough until the distal portion **436** of stimulation lead **430** exits the distal opening (**390** or **410**, respectively) of the lead introduction tool **350**, **380** to be oriented generally parallel and closely adjacent to the hypoglossal nerve at a target stimulation site (e.g. A) with the electrode portion **440** facing toward the nerve and away from the skin (and underlying sensory nerves), as illustrated in FIG. **7**D. Next, while maintaining the position of the distal portion **422** (e.g. electrode array **442** in FIG. **8**B) stimulation lead **430**, the tool **350** is withdrawn proximally from tissues **404**, **405** to leave just stimulation lead **430** in place, as illustrated in FIG. **7**E. From this configuration, the proximal portion **421** of stimulation lead **430** is tunneled and/or maneuvered subcutaneously to extend from the neck region to a pectoral region, to achieve a general configuration similar to that shown in FIG. **1** for lead **52**.

In some embodiments, as shown in perspective view of FIG. **8**D and the sectional view of FIG. **8**E, a distal tip **364**A of a lead introduction tool **350**A includes a shell-like cover **480** protruding distally outward from the cannula body **360**A and is configured with a wall **482** to control the deployment of the protrusions **464** of the anchoring mechanism **462** of stimulation lead **430**. In particular, the wall **482** of cover **480** acts as a barrier to maintain the protrusions **464** in a collapsed position against or close too the back side **434** of the distal portion **436** of the stimulation lead **430** so that the protrusions **464** do not engage the surrounding tissue prior to proper positioning of the stimulation electrode portion **440** against the hypoglossal nerve. At the same time, the distal portion **364** continues to define an opening **365**A generally opposite the cover **480** to enable exposing the electrode array **442** to the target nerve to allow testing or confirming positioning over the target stimulation site prior to deploying the anchor mechanism **462**. In some embodiments, the cover **480** defines a half-circular cross-sectional shape having a diameter (D**3**) generally corresponding to a diameter of cannula **360**. Once proper positioning of the stimulation electrode **440** has been achieved and upon proximally withdrawing the tool **350**A, the cover **480** is withdrawn from its position over anchoring mechanism **462**, thereby releasing protrusions to engage surrounding tissues. Likewise, in the event that the stimulation lead **430** must be removed, the cover **480** of the lead introduction tool **350** will force the collapse of the protrusions **464** (against the body of the distal portion **436** of the stimulation lead **430**) as the distal portion **436** of the stimulation lead **430** is withdrawn proximally into the lead introduction tool **350**A.

In another aspect, once implanted, a stimulation system for automatically treating obstructive sleep apnea will preferably remain in a stable position to endure the normal activities of the patient. For example, the neck of a patient moves through a wide range of motion through many different positions. To counteract the potential for a stimulation lead to move back and forth along the hypoglossal nerve (relative to a desired stimulation site), the anchoring mechanism **462** anchors the distal portion **436** of the stimulation lead **430** at the target stimulation site of the nerve. Accordingly, this anchoring mechanism insures that proper placement of the stimulation lead is maintained despite the dynamic motion and varying positions of the neck, which could otherwise cause inadvertent repositioning of the stimulation lead (relative to the target nerve) if the distal anchoring mechanisms were not present.

In addition, as previously noted, the anchoring mechanism **462** maintains this stable position without encircling the nerve (as a conventional cuff would) via an anchoring mechanism located on a directly opposite side of the distal portion **436** of the stimulation lead **430** with the anchoring mechanism **462** engaging the surrounding tissue instead of engaging the nerve. Nevertheless, to the extent that the electrode portion **440** of the distal portion **436** remains in close proximity or contact with the nerve, this relationship also contributes to the stability of the distal portion **436** because the anchoring mechanism **462** (on the opposite side from the electrode portion **440**) is simultaneously securing the distal portion **436** in its desired position.

Accordingly, in some embodiments, as shown in FIG. **9**, a second anchoring mechanism **502** and/or third anchoring mechanism **504** is deployed to further stabilize the position of the stimulation lead **430** in addition to the first anchoring mechanism **462**. As shown in FIG. **9**, body portion **437** of stimulation lead **430** extends proximally from the electrode portion **440** and from the first anchoring mechanism **462** while the second anchoring mechanism **502** is positioned at a first distance (D**3**) away from the first anchoring mechanism **462**. The third anchoring mechanism **504** is spaced proximally by a second distance (D**4**) from the second anchoring mechanism **502**. As further shown in FIG. **9**, a first region **510** (including portion **437**) of simulation lead **430** extends between first anchoring mechanism **462** and second anchoring mechanism **502** while a second region **512** extends between second anchoring mechanism **502** and third anchoring mechanism **504**. Finally, a third region **514** of lead **430** extends proximally from third anchoring mechanism **504** for passage toward the IPG (**55** in FIG. **1** or **109** in FIG. **2**).

In some embodiments, both the first region **510** and the second region **512** of the lead body **437** are pre-shaped into a serpentine or S-shaped configuration prior to deployment. In this pre-shaped configuration, first region **510** has a first length (D**3**) while second region **512** has a second length (D**4**). Once deployed via tunneling subcutaneously in a pathway proximally from the stimulation site, the S-shaped first and second regions **510**, **512** provide strain relief mechanisms that act in concert with the first, second, and third anchoring mechanisms **462**, **502**, **504** to stabilize the position of the stimulation lead **430** while compensating for movements of the body as described above.

FIG. **10** is a side plan view of a stimulation lead including a dynamic anchoring system **525**, according to an embodiment of the present disclosure. As shown in FIG. **10**, system **525** includes a first anchor **530**, second anchor **532**, and a third anchor **534** with portions **510** and **512** of a stimulation lead interposed between the respective anchors. In one embodiment, one, two, or three of the anchors **530**, **532**, **534** include a biomediating mechanism, that is, a mechanism to induce fibrotic growth in the surrounding tissue at which the respective anchor is located and thereby further anchor the distal portion of a stimulation lead. As shown at **540** in FIG. **10**, the anchors **530-534** comprise one or more of tines, mesh (e.g. Dacron mesh), barbs, flaps, and the like that are configured to mechanically engage the surrounding tissue.

In addition, in some embodiments, one or more of the anchors **530**, **532**, **534** are configured to provide a surface sized or treated (coated) to induce fibrotic growth to further secure the anchor. The "biomediating" anchors are particularly advantageous in a method of percutaneous delivery because the anchors do not require suturing, and therefore, regions **514**, **512**, and **510** of the stimulation lead can be tunneled toward the IPG **55** in FIG. **1** (or IPG **109** FIG. **2**) without having to apply sutures when the anchors **530**, **532**, **534** arrive at their intended positions. However, it is understood that in some embodiments, minimally invasive suturing techniques can be applied as desired to further secure the respective anchors in place (during the initial period of fibrotic growth) to supplement the securing strength of the mechanical component (e.g., barbs, flaps, etc.) of the respective anchors.

FIGS. **11-14** schematically illustrate a method **550** of percutaneously delivering an electrode portion of a stimulation lead to a target nerve, according to an embodiment of the present disclosure. In viewing the FIGS. **11-14**, it will be understood that sizes and/or relative spacing of various components of the anatomy (e.g., a size or width of incision, nerves, muscles, skin layer, etc.) and/or components of the tools (e.g., barbs, rods, etc.) have been exaggerated for illustrative clarity to highlight application of the tool. This method achieves placement of the electrode portion without the generally disruptive, and more time consuming, conventional cut-down implantation procedure (which would typically include a full dissection around the target nerve). Moreover, it is understood that prior to deployment of method **550**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; (2) make an incision to provide a skin entry point generally over the optimal stimulation site; and (3) guide the distal portion of an introduction tool or implantation instrument to that optimal stimulation site.

As shown in FIG. **11**, method **550** includes making an incision **553** through the skin **552** and through first muscle layer **554** to provide access to the previously identified optimal stimulation site at target nerve **558**, such as the hypoglossal nerve. The incision is relatively small, such as 2 centimeters wide, so that the access to the nerve **558** is considered minimally invasive. Next, via use of an implantation instrument **560**, an electrode portion **565** of a stimulation lead **568** is inserted through the incision **553** and guided to the nerve **558**. As shown in FIG. **12**, the implantation instrument **560** includes a distal tip **562** from which a selectively deployable, engagement mechanism **570** protrudes and a barrel **563** extending proximally between a handle **564** and distal tip **562**. The barrel **563** is configured to support deployment of the engagement mechanism **570**. A trigger **561** mounted at handle **564** is connected to a proximal end of the engagement mechanism **570** and controls selective deployment of the engagement mechanism **570**.

Moreover, in one embodiment, as shown in FIG. **13**, the electrode portion **565** comprises an insulative carrier **580** supporting an array of spaced apart electrodes **582** aligned in series. The carrier **580** also includes an array of securing elements **584**A, **584**B, **584**C, **584**D extending outward from the sides and/or ends of the carrier **580** to facilitate securing the carrier **580** relative to the surrounding tissues adjacent the hypoglossal nerve. The securing elements **584**A-**584**D can be loops or any other structure to which a suture or fastener is securable relative to the surrounding tissue. In this way, the electrodes **582** of the electrode portion **565** become secured relative to nerve **558** with the electrodes **582** facing the nerve **558**. In one embodiment, the electrodes **582** are aligned with a longitudinal axis of the electrode portion **565** and/or of the stimulation lead supporting the electrode portion **565**. As previously noted, the electrode portion **565** is implanted so that the electrodes **582** also face away from the skin **552** (with carrier **580** acting as a shield) to minimize stimulation of sensory nerves at or near the skin **552**.

In one aspect, as shown in FIG. **13**, the electrodes **582** have a width W2 (at least 3-5 millimeters) generally equal to or greater than a diameter of the target nerve (e.g., 3 millimeters) while carrier **580** has a width (W3) substantially greater than the width W2 of the electrodes **582** to insure shielding of the skin from the stimulation signal emitted from electrodes **582**.

Referring again to FIG. **11**, once the electrode portion **565** is properly positioned over the nerve **558**, the implantation instrument **560** secures the electrode portion **565** in position relative to the nerve **558** via engagement mechanism **570**. While the engagement mechanism **570** can take many different forms, in one embodiment shown in FIG. **14**, the anchoring mechanism **570** protrudes from the distal portion **562** of barrel **563** of implantation instrument **560**.

In particular, the anchoring mechanism **570** includes one or more small diameter rods **572** extending longitudinally within a conduit formed by barrel **563** with each rod **572** supporting a needle **574** configured to selectively extend distally from an end of each respective rod **572**. In one embodiment, barrel **563** includes a generally hollow, elongate tubular member, and the rods **572** extend through a length of the barrel **563** while being longitudinally movable within the barrel **563**.

Each needle **574** includes a barb **576** removably mounted at a distal end **575** of the needle **574**. In one embodiment, barbs **576** are made from a stainless steel material or a plastic material while having a relatively small length and/or diameter (e.g., 1-3 millimeters) to avoid patient discomfort. In addition, a suture **575** includes a first end connected to the barb **576** and a second end connected to securing elements **584** of electrode portion **565** of the stimulation lead. In a pre-deployment state, the respective sutures **575** are in a relaxed state without tension. In one embodiment, needles **574** are formed of a metal, such as a Nitonol material.

Accordingly, with the electrode portion **565** positioned over an optimal stimulation site of the nerve **558**, trigger **561** activates anchoring mechanism **570** to automatically cause the rods **572** to force the needles **574** to protrude distally outward and penetrate into surrounding tissues adjacent the nerve **558** and electrode portion **565**, and then the trigger **561** is subsequently relaxed causing retraction of rods **572** and their respective needles **574**. However, the barbs **576** remain fixed in the surrounding tissues because they detach from the needles **574** (at a point of detachment represented by dashed lines **579**) as the needles **574** are retracted. At this point, the implantation instrument **560** is removed from the incision site, leaving the electrode portion **565** in place.

In one aspect, as the needles **574** are advanced to place the barbs **576** into the tissue the sutures **575** become under tension, and as the needles **574** are retracted into barrel **563** with the barbs **576** remaining in the tissue, the sutures **575** remain under tension which effectively exerts tension on the carrier **580** to urge electrodes **582** into pressing contact against the nerve. For example, as schematically illustrated in the side view of FIG. **14**B, with barbs **576** deployed in tissue **590**, securing elements **584**B, **584**D (and their respective sutures **575**) are under tension, thereby urging electrode portion **565** (and particularly electrodes **582**) against the nerve **592**. This arrangement provides longitudinal stability to the secured position of the electrode portion **565** relative to the nerve. While not shown it is understood that the securing elements **584**A, **584**C on the opposite side of the electrode portion **565** also would be deployed via sutures **575** and barbs **576** so that all four securing elements **584**A, **584**B, **584**C, **584**D of electrode portion **565** are deployed. Accordingly, when secured under tension relative to the tissue **592** (via sutures **575** and barbs **576**), securing elements **584**A and **584**C also provide longitudinal stability to the position of the electrode portion **565** relative to the nerve **590**.

Moreover, in such an arrangement, securing element **584**A and securing element **584**B are positioned on opposite sides of the electrodes **582** to straddle the nerve **592**, thereby insuring lateral stability of the electrode portion **565**. Likewise, securing element **584**C and securing element **584**D are positioned on opposite sides of the electrodes **582** to straddle the nerve **592**, thereby insuring lateral stability of the electrode portion **565**.

In some embodiments, as shown in FIG. **14**B, the securing elements **584** are made of a flexible material to permit their bending toward the tissue to facilitate securing the barbs **576** and sutures **575** under tension. In these embodiments, the carrier **580** supporting the securing elements **584** can be either substantially rigid as shown in FIG. **14**B or can be generally flexible as shown in FIG. **14**C. In particular, as shown in the schematic sectional view of FIG. **14**C, an electrode portion **565** includes a flexible carrier **581** supporting electrodes **582** with the carrier **581** configured to flexibly conform to the arcuate shape of the cross-section of the nerve **558**. This arrangement insures close contact of the electrode **582** relative to the nerve **558** and accentuates the application of tension on sutures **575** when barbs **576** are anchored into the surrounding tissue **590**. In another aspect, it will be clear from a consideration of both FIGS. **14**B and **14**C, the securing elements include a first array of barbs for deployment on one side of the electrode portion **565** and a second array of barbs for deployment on an opposite side of electrode portion **565**.

After securing the electrode portion **565**, the implantation instrument **560** is removed and the lead body **567** of the stimulation lead **568** is delivered subcutaneously, via a tunneling tool, from the anchored site of the electrode portion **565** to the IPG **55** (FIG. **1**).

Various configurations of stimulation electrode portions of a stimulation lead are described and illustrated in association with the embodiments of FIGS. **15-27**. These various stimulation electrode portions can be delivered percutaneously or via other suitable delivery techniques. In some embodiments, the electrode portions and/or supporting proximal portions of the stimulation lead are configured to have a minimal mechanical impact on the nerve and the surrounding tissues and/or are configured to be implanted via minimally invasive techniques.

FIGS. **15-17**B schematically illustrate stimulation system including a bio-absorbable electrode portion **601** of a stimulation lead **600**, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion **600**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200** shown in FIG. **3**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

As shown in FIG. **15**, stimulation lead **600** comprises an electrode portion **601** including cuff **602** and electrodes **610**, as well as wires **612**, anchor **614**, and non-absorbable portion **620** of stimulation lead **600**. In one embodiment, the cuff **602** comprises a generally elongate tubular member that carries electrodes **610** and is configured to wrap around nerve **625** in a releasably secured manner with a generally cylindrical shape, thereby maintaining electrodes **610** in close contact against nerve **625**. A wire **612** extends proximally through the cuff **602** from each of the respective electrodes **610** and has a length extending further to anchor **614** and non-absorbable portion **620** so that the wires **612** are in electrical communication with IPG **55** (FIG. **1**).

In some embodiments, as shown in FIG. **17**A, each electrode **610** includes a conductive contact portion **616** and an electrically insulative cover **618**. The electrically insulative cover **618** extends over the top portion **639** of the contact portion **616**, extends beyond all four sides of contact portion **616**, including sides **635**, **637** viewable in FIG. **17**A. At a proximal end **634** of the electrode **610**, a strain relief member **636** connects wire **612** to contact portion **616** via wire **611**. In one embodiment, electrodes **610** are embedded in the cuff **602** with bottom portion **638** exposed at inner surface of cuff **602**. In some embodiments, electrodes **610** are aligned such that a longitudinal axis of each electrode **610** is generally perpendicular to a longitudinal axis of the cuff **602** and the respective electrode **610** are spaced apart from each other along a length of the cuff **610**.

In one aspect, cuff **602** is made of a bio-absorbable material so that over a period of several weeks following the implantation of electrode portion **601**, the cuff **602** is absorbed by the body, thereby leaving the electrodes **610** in their desired position relative to nerve **625**. At the same time that the cuff **602** is being absorbed, tissue growth occurs at and around the wires **612** and occurs at and around the electrodes **610** as they become exposed from absorption of cuff **602**. In some embodiments, wires **612** are arranged with several coiled portions **613** (highlighted in the enlarged caption in FIG. **15**) to further induce fibrotic tissue growth at and around the wires **612** such that tissue growth at each coiled portion acts as a separate anchor. After the absorption process for cuff **602** (and any other bio-absorbable components) is complete, the fibrotic tissue growth is sufficient to act as an anchoring mechanism to maintain the position of the electrodes **610** in their generally spaced apart relationship at the intended stimulation site and to secure the wires **612** to further maintain the position of electrodes **610**. The resulting arrangement is illustrated in FIG. **16** and FIG. **17**B. In the sectional view of FIG. **17**B, fibrotic tissue growth **642** surrounds the electrode **610** and wires **612** to mechanically secure the electrodes **610** in position over nerve **625** beneath skin/muscle portion **640**. As further shown in FIG. **17**B, insulative cover **618** protects each electrode **610** from the tissue growth **642**. In one aspect, the insulative cover **618** covers a top portion and sides of each electrode **610** while a bottom portion of each electrode element **610** remains exposed to nerve **625**. In some embodiments, the outer surface of insulative cover **618** includes a coating configured to induce the fibrotic tissue growth.

In one aspect, by employing a bio-absorbable cuff and inducing tissue growth to secure electrodes **610**, this system provides minimal long-term impact at the implantation site. In particular, the implanted, cuff-less set of electrodes **610** will be comfortable for the patient because of the absence of the relatively bulky size of a conventional cuff. This cuff-less arrangement also will be less likely to induce inadvertent mechanical effects on the target nerve (as compared to a conventional cuff electrode system), which can affect nerve function and comfort.

In some embodiments, anchor **614** is also made of bio-absorbable material and is absorbed over time within the body. Accordingly, tissue growth also would occur in this region to further secure wires **612** in place.

However, in some embodiments, as shown in FIGS. **15-16**, the stimulation lead **600** includes a non-absorbable fastener **622** configured to maintain the separate wires **612** in a grouped arrangement. In one aspect, fastener **622** insures an orderly transition of the separate wires **622** to the permanent lead portion **620** that extends to the IPG **55** (FIG. **1**). In another aspect, fastener **622** also provides strain relief to prevent inadvertent pulling of wires **612** on the target nerve. However, in other embodiments, this fastener **622** is omitted or is made of a bio-absorbable material.

FIGS. **18-21** schematically illustrate a bio-absorbable electrode portion **650** of a stimulation lead, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion **650**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site. Finally, it is also understood that the electrodes **660** of electrode portion **650** would be electrically connected via wires and a lead body to an IPG **55** (FIG. **1**) and that this general arrangement is omitted in FIGS. **18-21** for illustrative clarity.

FIGS. **18-19** are plan views of an electrode portion **650** of a stimulation lead in which the electrode portion **650** includes a generally flexible coil member **651** and electrodes **660**. In general terms, the coil member **651** wraps around a nerve **663** and defines a stent-like insulative member that maintains electrodes **660** in close contact against nerve **663**. However, unlike a conventional cardiovascular stent which is deployed within a blood vessel via expanding the stent outward against the wall of the blood vessel, the coil member **651** is configured to wrap around an outer surface of a nerve **663** in a self-sizing relationship and is not configured to expand radially when deployed in the desired position.

In some embodiments, the coil member **651** forms a generally helical shape and includes a pair of spaced apart rails **652** with numerous struts **654** extending between and interconnecting the rails **652**. In one embodiment, the rails **652** and struts **654** are made of non-conductive materials. In one aspect, electrodes **660** are sized and shaped to extend between a pair of rails **652**, as shown in FIGS. **18-19**, in a manner similar to the struts **654**. In one embodiment, the electrodes **660** are in general alignment with a longitudinal axis of the coil member **651**. However, it will be understood that the coil member **651** is not strictly limited to the arrangement of rails **652** and struts **654** shown in FIGS. **18-19** because numerous variations and arrangements of struts can be used to form the helically shaped coil member.

As shown in its pre-deployment state in FIG. **18**, coil member **651** has an inner diameter (D**6**) that is substantially less than a diameter (D**5**) of the target nerve **663** (see also FIG. **19**). Accordingly, when coil member **651** is placed about the larger diameter nerve **663**, the coil member **651** wraps about the nerve **663** in a self-sizing manner such that the inner diameter of the coil member **651** substantially matches the diameter of the target nerve **663**, as shown in FIG. **19**. To the extent that any spacing is shown between the coil member **651** and nerve **663** in FIG. **19**, this spacing is provided for illustrative clarity to clearly define the components of the coil member **651** separately from nerve **663**.

In some embodiments, the coil member **651** attracts tissue growth at rails **652** and struts **654** with the combination of the tissue growth and the rails **652** and struts **654** acting as an anchoring mechanism to maintain the electrodes **660** in close contact against nerve **663**.

In some other embodiments, the coil member **651** forms a bio-absorbable material so that after absorption of rails **652** and struts **654** takes place, electrodes **660** remain in close contact to nerve **663** with tissue growth **670** on and around the electrodes **660** holding the electrodes **660** in place relative to the nerve **663**, as shown in FIGS. **20-21**. The various components (struts and rails) of the coil member **651** form a latticework or frame configured to induce fibrotic tissue growth in a pattern generally matching the structure of the coil member **651** so that the induced tissue growth forms in a mechanically advantageous framework holding the electrodes **660** in place relative to the nerve **663**. In one aspect, this framework of fibrotic growth forms a bio-cuff in which tissues produced within the body form a cuff to maintain the electrodes **610** in the desired position relative to the nerve.

It is understood that tissue growth also would occur at and around the wires (not shown) extending proximally from the electrodes **660** toward the IPG **55** (FIG. **1**). It is further understood, that similar to previous embodiments, an outer portion of the electrode **660** (the portion that does not contact the nerve **663**) would include an insulative cover to act as a barrier between the contact portion of the electrode **660** and the surrounding tissue.

Moreover, in one embodiment, each electrode **660** is connected to a respective one of an array of wires with each respective wire connected to, and extending to, a stimulation lead body configured for electrical communication with an IPG **55** (FIG. **1**). In one embodiment, the array of wires includes substantially the same features and attributes as the array of wires **612**, as previously described and illustrated in association with FIGS. **15-16**.

FIGS. **22-24** schematically illustrate an electrode portion **700** of a stimulation lead, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion **700**, one or more potential stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

As shown in FIGS. **22-23**, electrode portion **700** includes a carrier **702** supporting generally spike-shaped electrodes **710** that are spaced apart from each other along a length of the carrier **702**. The carrier **702** includes a distal end **704** and a proximal end **706** while each electrode **710** forms a conductive member including an exposed distal tip **714** and an insulative covered base portion **712**. While just two electrodes **710** are shown, it will be understood that in other embodiments, carrier **702** supports more than two electrodes **710**. In one embodiment, the carrier **702** comprises a generally flat member having a first side and a second side (opposite the first side), with the electrodes **710** extending generally outward from the first side of the generally flat member.

In another aspect, for each electrode **710**, a separate wire **720** extends through the carrier **704** (shown as dashed lines in FIG. **23**) and is electrically connected to the base portion **712** of each respective electrode **710**. It is further understood that the electrodes **710** are formed of ultra fine wires, as known to those skilled in the art, and that the electrodes **710** are shown in FIGS. **22-24** in an exaggerated, enlarged form strictly for illustrative purposes.

Once the electrode portion **700** is delivered to the intended stimulation site, pressure is applied to insert the distal tips **714** of the respective electrodes **710** into the nerve **730**. Because of the small dimensions of the ultra fine wire forming each electrode **710**, the electrodes **710** are maintained in this position via the tissue of the nerve effectively capturing the electrodes **710**. With this arrangement, close contact of the electrodes **710** to the nerve **730** is insured, resulting in effective stimulation of the nerve **730**.

In some embodiments, once the electrode portion **700** is secured in place, the electrode portion **700** attracts tissue growth (not shown) about carrier **702** and base portion **712** of needles **710** with the combination of the tissue growth and the carrier **702** and base portions **712** acting as an anchoring mechanism to maintain the electrode tips **714** in penetrating engagement (i.e. inserted engagement) relative to nerve **730**.

In some other embodiments, the carrier **702** forms a bio-absorbable material so that carrier **702** is absorbed over time, leaving just electrodes **710** and wire portions **721**, **720** in place at nerve **730**, as shown in FIG. **24**. As the absorption of carrier **702** occurs, electrodes **710** are held in inserted engagement relative to nerve **730** because of tissue growth (not shown) forming on and around the base portion **712** of electrodes **710** (as the carrier is absorbed) to hold the electrodes **710** in penetrating engagement relative to the nerve **730**. It is understood that a similar tissue growth would occur at and around the wire portions **721** and **720** extending proximally from the electrodes **660** toward the IPG **55** (FIG. **1**).

FIGS. **25-32** schematically illustrate stimulation system **800** and a method of implanting components of system **800**, according to an embodiment of the present disclosure. As shown in FIGS. **25-27**, the stimulation system **800** includes at least an electrode portion **801** of a stimulation lead **802** and a shield **804**. It is understood that prior to deployment of electrode portion **801**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200** shown in FIG. **1**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

As shown in FIG. **25**, stimulation lead **803** includes electrode portion **801** and lead body **808** with the electrode portion **801** including a generally elongate carrier body extending between a distal end **817** and a proximal end **816**, and an electrode strip **815**, which includes an array **818** of electrodes **820** spaced apart along a length of the carrier body. The lead body **808** extends proximally from electrode portion **801** and includes an anchor **810** with a proximal lead portion **812** configured for extension to and electrical connection to an IPG (**55** in FIG. **1** or **109** in FIG. **2**).

The electrode strip **815** has a length (L**2**) substantially greater than a diameter of a nerve, and sufficient to extend across a diameter of a nerve **840** and outward from both sides of the nerve **840**, as shown in at least FIGS. **26-27**. In one embodiment, the length (L2) is at least twice the diameter of the nerve. In another embodiments, the length (L2) is at least three times the diameter of the nerve, such that with an expected nerve diameter of about 3 millimeters, the electrode strip **815** has a length (L2) of about 9 millimeters. In this embodiment, about 3 millimeters of the full length of the electrode strip **815** would be in close proximity or contact with the nerve **840** while about 3 millimeters of the length of the electrode strip **815** would extend outward from each side of the nerve **840**, as schematically illustrated in FIGS. **26-27**. In some embodiments, electrode strip **840** has a width (W4) of about 3 millimeter, which facilitates a minimally invasive implantation method in some embodiments (as will be later described in more detail in association with FIGS. **30-32**). In comparison, a conventional cuff electrode might typically have a width of about 9 millimeters.

In use, the electrode portion **801** is delivered to an intended stimulation site along the hypoglossal nerve **840** and with the electrode strip **815** having a generally perpendicular orientation relative to a longitudinal axis (represented by line A) of the nerve **840** (in the region of the intended stimulation site), as shown in FIG. **26**. In one embodiment, as illustrated in the sectional view of FIG. **27**, the electrode portion **801** is positioned so that the electrodes **820** of electrode strip **815** faces toward nerve **840** to apply the stimulation signal onto the nerve **840**. Moreover, in some embodiments, each electrode **582** is independently programmable or controllable via IPG **55** (FIG. **1**) in a manner substantially similar to previously described embodiments to allow control and adjustment over the stimulation signal without re-positioning the electrode strip **815**. In addition, an insulative shield **804** is interposed between the nerve **840** and skin **830** (and underlying muscle **832**) such that the shield **804** permits application of the stimulation signal on the nerve **840** while preventing application of the stimulation signal on the skin **830**.

In this arrangement, nerve **840** is sandwiched between the electrode strip **815** and insulative shield **804** and the electrode portion **801** is deployed so that at least a portion of the electrode strip **806** extends, in close proximity to or in close contact with, about the outer surface of the nerve **840**, as shown in the sectional view of FIG. **27**. However, in this sandwiched arrangement, each of the electrode strip **815** and shield **804** are secured independently relative to the surrounding tissue such that neither electrode strip **815** nor shield **804** are secured to the nerve **840**. For example, in one embodiment, electrode strip **815** is secured at each of its ends, via anchors (represented by x **878** and x **879** in FIG. **26**), relative to the surrounding tissue and independent of nerve **840**. With the generally perpendicular orientation of both the electrode strip **815** and the shield **804**, this configuration permits movement of the nerve **840** in a lateral direction (represented by arrow M) relative to both the electrode strip **815** and the shield **804**, thereby accommodating shifting of the nerve **840** as the neck of the patient moves through a wide range of motion through many different positions.

With this in mind, upon lateral movement of nerve (along arrow M), both the electrode strip **815** and shield **804** remain stationary such that the sandwiched arrangement is maintained even when nerve **840** moves. Accordingly, because of the electrode strip **815** has a length (L2) that is substantially longer than the diameter of nerve **840**, in any lateral position of the nerve **840** (within a natural, limited range of motion) the electrode strip **815** remains in a position to apply an efficacious stimulation signal to nerve **840**. Similarly, because the shield **804** has length (L3) substantially longer than the diameter of nerve **840** and substantially longer than the length (L2) of the electrode strip **815**, the shield is always positioned to block application of the stimulation signal to the skin **830** (and underlying sensory nerves). In one embodiment, shield **804** defines an area substantially greater than an area of an electrical field produced by electrodes **820** toward a skin surface.

While the electrode portion **801** extends generally perpendicular to the longitudinal axis of the nerve **840** (at the stimulation site), in some embodiments the lead body **808** extends generally parallel to the longitudinal axis of the nerve **840** to follow a path toward the IPG **55** (FIG. **1**). As previously noted, the lead body **808** includes an anchor **810** to permit securely anchoring the lead body **808** (and therefore the electrode portion **801** as well) relative to the anatomical structures and tissues nearby to the nerve **840**. From the anchor **810**, a proximal portion **812** of the lead body **808** extends further toward the IPG **55** (FIG. **1**) via a subcutaneous tunnel.

In some embodiments, the application of a perpendicular orientation of an electrode strip (e.g. electrode strip **815**) relative to nerve **840** is used with other cuff-less electrode configurations. For example, embodiments associated with FIGS. **11-14**C can be deployed to orient the electrode portion **565** to be generally perpendicular to the nerve such that the series of electrodes **582** are aligned transverse to a longitudinal axis of the target nerve without a cuff encircling the circumference of the nerve **840**. It will be understood that the number of electrode contacts will be adjusted, as appropriate, in the electrode portion **565** to insure capture of the nerve throughout a full cross-section (or diameter) of the nerve.

In further reference to FIGS. **25-29**, in some embodiments, electrode portion **801** includes one or more anchoring mechanisms. Accordingly, FIG. **28** is a top plan view of an electrode portion **850** including a series of electrode contacts **820**, a distal end **852**, and a proximal end **854**. At distal end **852**, one or more loops (or other securing elements) **860** are provided to enable suturing or otherwise fastening the distal end **852** relative to surrounding tissue adjacent the nerve **840**. Similarly, at proximal end **854**, one or more loops (or other securing elements) **870**, **872** are provided to enable suturing or otherwise fastening the proximal end **854** relative to surrounding tissue adjacent the nerve **840**. In this way, the electrode strip **850** is securable in a stable position close to nerve **840** (but independently of the nerve) without being secured to the nerve **840** itself and/or without encircling the nerve **840**.

In some other embodiments, as schematically illustrated in the sectional view of FIG. **29**, electrode strip **815** and shield **804** are secured together. In these embodiments, the sandwiched configuration of electrode strip **815** and shield **804** is maintained relative to nerve **840** to thereby permit lateral movement (directional arrow M) of nerve **840** while still providing electrical stimulation of nerve **840** via electrode strip **815** and while still protecting skin **830** via shield **804**. In particular, fastening mechanism **870** includes a first component **872** and a second component **874**, with each respective component **872**, **874** sized to extend between the electrode strip **815** and the shield **804**. In one non-limiting aspect, by providing first component **872** on one lateral side of nerve **840** (connected to the first ends of the respective strip and shield) and by providing second component **874** on an opposite lateral side of nerve **840** (connected to the second ends of the respective strip and shield), the fastening mechanism **870** provides a lateral boundary or barrier to insure that nerve **840** will remain between electrode strip **815** and shield **804** while permitting lateral movement of nerve **840**. In other embodiments, only one end of the respective electrode strip **815** and the shield **804** are secured together, leaving the other end open.

In one embodiment, the first component **872** of securing mechanism **870** comprises a buckle-belt mechanism that is connectable to the distal end **817** of electrode strip **815** and connectable to the distal end **805** of the shield **804**. Likewise, the second component **874** comprises a buckle-belt mechanism that is connectable to the proximal end **816** of electrode strip **815** and connectable to the proximal end **807** of the shield **804**.

In some embodiments, the combination of the shield **804** and the electrode strip **815** are delivered percutaneously in a minimally invasive implantation method, as schematically illustrated in FIGS. **30-32**. In particular, because the electrode strip **815** is quite narrow (e.g., 3 millimeters wide as shown in FIGS. **25-27**), the procedure begins via making two small incisions **880**, **882** in the skin **830** (and underlying tissues/muscles **832**) on opposite lateral sides of the underlying nerve **840**, as shown in FIG. **31**. At least one of the incisions **880**, **882** will have a width (W**6**) generally corresponding to the width (W**4** in FIG. **25**) of the electrode strip **815**. Using a forceps (not shown), the electrode strip **815** is maneuvered through incision **880** and via incision **882** (as represented via arrows E and R) until the electrode strip **815** is in position underneath nerve **840** with electrode contacts **820** in close contact with the nerve **840** and facing skin **830**, as shown in FIG. **30**. Next, using a similar technique involving incisions **880** and/or **882**, the shield **804** is introduced into a position interposed between nerve **840** and skin **830**. If necessary, either incision **880**, **882** can be widened slightly to accommodate introduction of the larger width (W**5**) of shield **804** through the respective incision. With this minimally invasive method of implantation, the sandwiched configuration of the electrode strip **815** and the shield **804** relative to the nerve **840** is achieved with minimal disruption to the skin and tissues above and near the nerve **840**. Accordingly, the combination of the electrode strip **815** and the shield **804** enable a minimally invasive method of implanting those elements while also providing a stimulation system that minimally impacts the natural state of the nerve by acting as a cuff-less electrode.

Several different embodiments have been described in association with FIGS. **1-14**, in which an IPG **55** is implanted in a pectoral region and in which a sensor electrode(s) and a stimulation electrode(s) (extending from the IPG **55**) are delivered percutaneously to sense respiratory patterns and to apply a stimulation signal, respectively. In addition, several embodiments of stimulation electrode arrays (and associated anchor mechanisms) have been described in association with FIGS. **15-32**. Moreover, it is understood that in some of these embodiments, a lead is percutaneously placed in each side of the body (left and right) such that bilateral (simultaneous or alternating) stimulation takes place on the left and/or right hypoglossal nerve (or other target nerve). With these various embodiments in mind, it is further understood that among those embodiments, several configurations are provided in which at least two electrodes are spaced apart in the body in the vicinity of the upper airway such that an impedance is measurable between the two spaced apart electrodes to provide an indication of airway patency (e.g., opening and/or closing of the upper airway). In some configurations, the spaced electrodes are both stimulation electrodes, while in other configurations, the spaced apart electrodes comprise one stimulation electrode and one respiratory sensor electrode. In yet other configurations, the two spaced apart electrodes (used for measuring an impedance indicative of airway patency) include one of the electrodes comprising at least one of a stimulation electrode and a respiratory sensor electrode and the other one of the electrodes comprising an electrode formed by an electrically conductive portion of a case or housing of the IPG **55**.

Moreover, in some embodiments, the respective electrode portions provide a dual function in that each electrode provides a respiratory sensing function or a stimulation function as well as acting as a part of a pair of impedance sensing electrodes. On the other hand, in other embodiments, at least one electrode of the pair of impedance sensing electrodes does not also act to sense respiration (e.g. inspiration) or to stimulate but rather is dedicated for use in sensing impedance to detect or indicate a degree of airway patency.

At least some embodiments of the percutaneously-delivered electrode portions (described herein) enable precise location of an electrode portion adjacent to an optimal neurostimulation site because the percutaneous approach enables the surgeon to vary the position of an electrode portion of a stimulation lead along the length of the hypoglossal nerve. In addition, this precise placement is performed in a minimally invasive manner unlike the anatomically disruptive conventional cut-down procedure for placing stimulation leads. The methods and systems of the present disclosure allows the surgeon to identify a precise optimal stimulation site that causes contraction of one or more specific muscles (suited to restore airway patency) prior to fixing the location of the electrode portion relative to the target nerve.

Embodiments of the present disclosure provide an implantable system to provide therapeutic solutions for patients diagnosed with obstructive sleep apnea. The system is designed to stimulate the hypoglossal nerve during inspiration thereby preventing occlusions in the upper airway during sleep.

While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that variations exist. It should also be appreciated that the exemplary embodiment or exemplary embodiments are only examples, and are not intended to limit the scope, applicability, or configuration of the present disclosure in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the exemplary embodiment or exemplary embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope of the present disclosure as set forth in the appended claims and the legal equivalents thereof.

The invention claimed is:

1. A method of implanting a stimulation lead to treat sleep-related disordered breathing, comprising:

percutaneously inserting a distal portion of a cannula and positioning the distal portion to be adjacent to a target nerve stimulation site while maintaining a proximal portion of the cannula external to a skin surface, wherein the target nerve stimulation site includes an airway-patency related nerve;

arranging a stimulation lead to include a distal portion having a first side and a second side opposite the first side, the stimulation lead including:

at least one anchor member positioned on, and biased to extend outwardly from, the second side in a deployment position;

at least one stimulation electrode on the first side;

slidably advancing the distal portion of the stimulation lead into and through the cannula to percutaneously insert the stimulation lead until a distal portion of the stimulation lead is positioned against the nerve at the target stimulation site, wherein slidable advancement of the distal portion of the stimulation lead into the proximal portion of the cannula causes the at least one anchor member to be releasably contained against a body of the second side of the stimulation lead in a storage portion;

arranging at least the distal portion of the cannula to have a generally tubular configuration;

arranging the cannula to include a distal extension, which extends distally from the distal tip of the generally tubular distal portion of the cannula,

wherein, in at least one slidable position of the stimulation lead relative to the cannula, releasably containing the at least one anchor member in the storage position comprises:

releasably covering the at least one anchor member via the distal extension of the cannula while simultaneously exposing the at least one stimulation electrode of the stimulation lead toward the nerve and

slidably removing the cannula, while maintaining the position of the distal portion of the stimulation lead at the target stimulation site, to cause the at least one anchor member to extend outwardly from the second side of the stimulation lead in the deployment position against tissue adjacent the distal portion of the stimulation lead.

2. The method of claim **1**, comprising:

arranging the second side of the distal portion of the stimulation lead to include an insulating element opposite the at least one stimulation electrode on the first side to prevent stimulation of tissue adjacent the second side of the distal portion.

3. The method of claim **1**, comprising:

arranging the at least one anchor member as an array of protrusions spaced apart along a portion of the length of the second side of the distal portion of the stimulation lead with the respective protrusions being generally opposite the at least one stimulation electrode on the first side.

4. The method of claim **3**, comprising:

arranging each respective protrusion as a barb.

5. The method of claim **1**, comprising:

arranging the distal portion of the cannula to include a flexible generally curved shape such that in a deployment position, an end of the distal portion cannula is oriented in a direction oriented at a generally obtuse angle relative to a longitudinal axis of a proximal portion of the cannula and in an insertion position, the flexible distal portion is configurable to assume an orientation generally parallel to the longitudinal axis of the proximal portion of the cannula.

6. The method of claim **5**, comprising:

upon positioning the distal portion of the stimulation lead at the target stimulation site, causing the flexible distal portion of the cannula to assume the generally curved shape.

7. The method of claim **6**, comprising:

locating an entry point of the cannula into the skin surface at a first distance away from the target stimulation site, wherein the first distance is generally equal to a sum of:

a second distance between the end of the cannula and a longitudinal axis of the proximal portion of the cannula when the distal portion is in the deployment position; and

a third distance corresponding to at most a length of an electrode portion of the stimulation lead.

8. The method of claim **6**, comprising:

via a percutaneous access, advancing a proximal portion of the stimulation lead from the target stimulation site to a pectoral region of a patient.

9. The method of claim **1**, comprising:

arranging the distal portion of the cannula to include a generally rigid, straight portion having an opening oriented generally perpendicular to a longitudinal axis of the cannula;

wherein slidably advancing the stimulation lead into and through the cannula causes the distal portion of the stimulation lead to extend out of the end of the opening of the cannula in an orientation at a generally obtuse angle relative to the proximal portion of the cannula.

10. The method of claim **9**, comprising:

locating an entry point of the cannula into the skin surface at a first distance away from the target stimulation site, wherein the first distance is generally equal to a second distance corresponding to at most a length of an electrode portion of the stimulation lead.

11. The method of claim **1**, comprising:

upon advancing the cannula, measuring a depth of insertion of the distal portion of the stimulation lead via graduation markings spaced apart along a length of the cannula.

12. The method of claim **1**, comprising:

percutaneously inserting a test needle at a plurality of test stimulation sites, including the target stimulation site, wherein the test needle is separate from and independent of the cannula and the test needle is separate from, and independent of, the stimulation lead;

determining the target stimulation site from among the plurality of test stimulation sites via applying, at each respective test stimulation site, a stimulation signal;

monitoring, during application of the stimulation signal, at least one of:

occurrence of a tongue protrusion or tongue retraction;

change in a cross-sectional area of an upper airway;

a lack of response in non-target muscles;

a twitch in a tongue muscle or laryngeal muscle; or

strongest electromyography response for a target muscle.

13. The method of claim **12**, comprising:

identifying, based on the determined target stimulation site, a percutaneous access pathway to the target stimulation site.

14. The method of claim **1**, comprising:

evaluating the target nerve stimulation site via varying an array of stimulation parameters, which include at least one of an amplitude parameter, a frequency parameter, a pulse width parameter, a polarity parameter, and a duration parameter.

15. The method of claim **12**, comprising:

arranging the test needle to include a distal portion and a proximal portion with the proximal portion including a handle releasably secured relative to the proximal portion, wherein the handle is sized to remain external to a skin surface and the needle has a length configured to percutaneously access a nerve.

16. The method of claim **15**, comprising:

arranging the cannula as a generally tubular member having a distal portion, a proximal portion, and configured to be slidably advanceable over the test needle.

17. The method of claim **12**, comprising:

arranging at least one of the test needle, the cannula, and the stimulation lead include at least one radiopaque marker configured to identify, under fluoroscopy, an orientation and position of the respective test needle, cannula, or stimulation lead.

18. The method of claim **12**, comprising:

arranging an intermediate portion of the test needle to include a series of graduation markings spaced apart along a portion of a length of the test needle and positioned to gauge a depth of insertion of the test needle percutaneously.

19. The method of claim **12**, comprising:

providing a response monitor in communication with the test needle and in communication with one or more physiologic sensors; and

using the response monitor to identify a muscle-based physiologic response upon application of a nerve stimulation signal via the test needle.

20. The method of claim **1**, wherein the at least one stimulation electrode comprises an array of stimulation electrodes, the array including more than three stimulation electrodes from which an operative set of electrodes is selectable at any given time.

21. The method of claim **3**, comprising:

arranging at least some of the respective protrusions to extend in a first direction that diverges from a second direction in which at least some other of the respective protrusions extend.

22. The method of claim **3**, comprising:

performing the percutaneous insertion of the stimulation lead, via the cannula, external to a blood vessel.

23. The method of claim **1**, comprising:

arranging the at least one anchor member on the second side of the distal portion of the stimulation electrode to be isolated from the nerve against which the at least one stimulation electrode is positioned.

24. A method of implanting a stimulation lead to treat sleep-related disordered breathing, comprising:

percutaneously inserting a distal portion of a cannula and positioning the distal portion to be adjacent to a first target nerve stimulation site while maintaining a proximal portion of the cannula external to a skin surface, wherein the first target nerve stimulation site includes an airway-patency related nerve;

arranging a stimulation lead to include a distal portion having a first side and a second side opposite the first side, the stimulation lead including:

at least one anchor member positioned on, and biased to extend outwardly from, the second side;

at least one stimulation electrode on the first side;

slidably advancing the distal portion of the stimulation lead into and through the cannula until a distal portion of the stimulation lead is positioned against the nerve at the first target nerve stimulation site, wherein slidable advancement of the distal portion of the stimulation lead into the proximal portion of the cannula causes the at least one anchor member to be releasably contained against a body of the second side of the stimulation lead in a storage portion;

arranging the cannula to include a distal extension, which extends distally from the distal tip of the generally tubular distal portion of the cannula,

wherein, in at least one slidable position of the stimulation lead relative to the cannula, releasably containing the at least one anchor member in the storage position comprises releasably covering the at least one anchor member via the distal extension of the cannula while simultaneously exposing the at least one stimulation electrode of the stimulation lead toward the nerve,

with the stimulation lead in the at least one slidable position, maneuvering a combination of the stimulation lead and the cannula together along the nerve and periodically applying a test stimulation signal to identify the first target nerve stimulation site from among a plurality of test stimulation sites along a length of the nerve; and

slidably removing the cannula, while maintaining the position of the distal portion of the stimulation lead at the first target nerve stimulation site, to permit the at least one anchor member to extend outwardly from the second side of the stimulation lead in a deployment position against tissue adjacent the distal portion of the stimulation lead.

25. The method of claim **24**, wherein identifying the first target nerve stimulation site comprises:

varying an array of stimulation parameters at each test stimulation site, the respective stimulation parameters including at least one of an amplitude parameter, a frequency parameter, a pulse width parameter, a polarity parameter, and a duration parameter.

26. The method of claim **25**, comprising:

arranging the at least one stimulation electrode to include a patterned array of more than three stimulation electrodes; and

performing the varying the array of stimulation parameters at each respective stimulation electrode to identify a first combination of respective stimulation electrodes for applying nerve stimulation at the first target nerve stimulation site.

27. The method of claim **26**, comprising:

selectively re-performing the varying of stimulation parameters at each respective stimulation electrode to identify a different, second combination of respective electrodes for applying nerve stimulation at the first nerve stimulation site, wherein at least some of the respective stimulation electrodes in the first combination are omitted in the second combination.

28. The method of claim **26**, comprising:

re-positioning the stimulation lead along the nerve; and

selectively re-performing the varying of stimulation parameters at each respective stimulation electrode to identify a different, second combination of respective electrodes for applying nerve stimulation at a second nerve stimulation site different than the first nerve stimulation site.

29. The method of claim **1**, wherein the at least one stimulation electrode is located only on the first side.

30. The method of claim **29**, wherein the at least one anchor member is located only on the second side.

31. The method of claim **2**, wherein the at least one stimulation electrode extends only on the first side of the distal portion.

32. The method of claim **31**, wherein the insulating element extends the entire length of the second side of the distal portion.

33. The method of claim **3**, comprising:

arranging each respective protrusion as a prong.

34. The method of claim **3**, comprising:

arranging each respective protrusion as a flap.

35. The method of claim **1**, wherein the distal extension comprises a half-circular cross-sectional shape and a distal end at which the cannula terminates, and wherein the cannula defines an opening opposite the distal extension to expose the at least one stimulation electrode.

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